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RESEARCH PROJECT INITIATION

Date: October 17, 1974

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Project No: E-21-646

Principal Investigator: Dr. M. E. Womble

Sponsor: Naval Coastal Systems Laboratory

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E-21-696
TASK I

Extracting Vehicle Transfer Function

From Flight Test Data

by

M. Edward Womble
21 January 1975

Georgia Institute of Technology
School of Electrical Engineering

This report was prepared for the Naval Coastal Systems Laboratory under Contract No. N61331-75-M-0610. The NCSL technical monitor for this task was Dr. Douglas E. Humphreys.

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1. Introduction

In designing control systems for underwater and surface craft, one requires the transfer functions describing the relationships between the control inputs--rudder, stern plane, propellers, etc.--and the outputs describing the state of the craft--position, velocity, attitude, etc. The ultimate objective of this study is to develop algorithms capable of extracting the desired transfer functions from flight-test data. This task, which is merely the first step, involves

1) developing the capability of processing flight test data recorded on magnetic tape,
2) developing navigation algorithms for smoothing the data and producing estimates of the state of the craft, and
3) putting existing identification algorithms by Taylor on the Georgia Tech Univac 1100 computer and verifying that they work.

Once this preliminary task has been accomplished, the problems involved with identifying the craft's transfer functions from the flight-test data can be investigated. These problems include, but are not limited to, widely different time constants for various modes, various degrees of coupling between modes, and unwanted noise in the original data.

The remaining portion of this report addresses how we have gone about accomplishing the three preliminary subtasks--processing the flight-test data, smoothing the data with a navigator, and putting Taylor's identification program on our Univac 1100 computer--and suggests how we would propose to continue our effort.

2. Equations of Motion

In the first phase of this task we will not only assume the earth is nonrotating, we will assume the earth is flat! For the short period of time we are considering (< 5 minutes) and the small distances involved (< 5 nautical miles), these assumptions are reasonable.(1) They allow us to make two considerable simplifications. First, we can consider the initial local level coordinate frame (x_0 and y_0 in the initial local level plane with z_0 perpendicular to the plane and pointed down. x_0 is pointed along the initial heading and y_0 is pointed so that x_0, y_0, z_0 is an orthogonal right-handed system) to be an inertial frame. Secondly, the actual initial heading is insignificant; therefore, we will always assume the initial heading is zero degrees (on a flat earth, it makes no difference whether or not we head north, east, south, etc.).

2.1 Coordinate Transformation

All of the forces are known in the initial local level frame; however, in order to take advantage of the mass symmetries of the vehicles and to get time invariant moments of inertia, the equations of motion are coordinated in the body frame. Furthermore, some of the measurements used are from body mounted gyros and accelerometers. Therefore, we must transform vectors from the initial local level frame to the body frame.

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(1). Bernard Etkin, Dynamics of Atmospheric Flights, John Wiley and Sons, Inc., New York, 1972, pp. 145-151.

The Euler angles used to keep up with the orientation of the vehicle with respect to the initial local level frame are Ψ (yaw), Θ (pitch), and Φ (roll), see Figure 2.1. From Figure 2.1, we obtain the desired

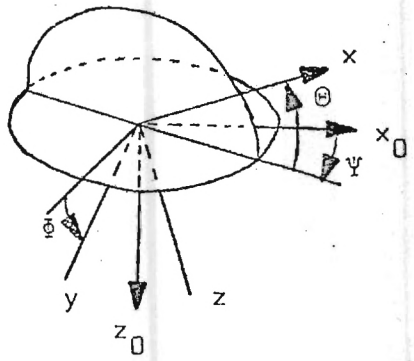

Figure 2.1 Orientation of the vehicle (x,y,z) with respect to the initial local level frame (x_0,y_0,z_0)

transformation matrix. It is[1]

$$C_{\ell}^{b} = \begin{bmatrix} C\Theta C\Psi & C\Theta S\Psi & -S\Theta \\ C\Psi S\Theta S\Phi - S\Psi C\Phi & C\Psi C\Phi + S\Psi S\Theta S\Phi & C\Theta S\Phi \\ C\Psi S\Theta C\Phi + S\Psi S\Phi & S\Psi S\Theta C\Phi - C\Psi S\Phi & C\Theta C\Phi \end{bmatrix} \qquad (2.1)$$

where $C\Theta = \cos\Theta$, $S\Phi = \sin\Phi$, etc.

---

1. Etkins op.cit., p. 117

2.2 Nonlinear Equations

The general nonlinear equations defining the motion and attitude of the vehicle are[1]

$$p_\ell^2 \vec{r} = \vec{g} - \vec{f} \tag{2.2}$$

and

$$p_\ell \vec{H} = \vec{M} \tag{2.3}$$

where 1) p_ℓ designates the time derivative with respect to the local level frame.

2) $\vec{g}$ is the acceleration due to gravity.

3) $\vec{f}$ is the nongravitational specific force.

4) $\vec{H}$ is the vehicles angular momentum.

5) $\vec{M}$ is the torque applied to the vehicle.

Using Coriolis' theorem, we can express (2.2) and (2.3) as[2]

$$p_b \vec{v} = (\vec{g} - \vec{f}) - \vec{\omega}_{\ell b} \times \vec{v} \tag{2.4}$$

and

$$p_b \vec{H} = \vec{M} - \vec{\omega}_{\ell b} \times \vec{H} \tag{2.5}$$

where 1) p_b is the time derivative with respect to the body frame.

2) $\vec{v} = p_\ell \vec{r}$

3) $\vec{\omega}_{\ell b}$ is the angular velocity of the vehicle with respect to the local level frame.

1. W. Wrigley, W. M. Hollister and W. G. Denhard, C. Theory, Design and Instrumentation, MIT Press, Cambridge, Mass., 1969, p. 33.

2. R. L. Halfman, Dynamics, Addison-Wesley Publishing Company, Inc., Reading, Mass., 1962.

Equations (2.4) and (2.5) coordinatized in the body frame become

$$\dot{\vec{v}}^b = C_\ell^b \vec{g}^\ell - \vec{f}^b - \vec{\omega}_{\ell b}^b \times \vec{v}^b \tag{2.6}$$

and

$$I^b \dot{\vec{\omega}}_{\ell b}^b = \vec{M}^b - \vec{\omega}_{\ell b}^b \times I^b \vec{\omega}_{\ell b}^b \tag{2.7}$$

where the superscript on the vectors imply they are coordinatized in the indicated coordinate frame, $\vec{H}^b = I^b \vec{\omega}_{\ell b}^b$, I^b is the inertia tensor with respect to the body frame, and $\dot{x}$ is simply (dx/dt). The actual position of the vehicle and its attitude are given by

$$\dot{\vec{r}}^\ell = C_b^\ell \vec{v}^b \tag{2.8}$$

and[1]

$$\dot{C}_\ell^b = C_\ell^b [\vec{\omega}_{\ell b}^b \times] \tag{2.9}$$

where

$$[\vec{r} \times] = \begin{bmatrix} 0 & -r_z & r_y \\ r_z & 0 & -r_x \\ -r_y & r_x & 0 \end{bmatrix}$$

(Observe that if we know C_ℓ^b, then we can solve for Φ, Θ and Ψ via (2.1).)

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1. Wrigley, op.cit., p. 23

2.3 Linearized Kinematics

Equations (2.6) - (2.9) are the equations of motion for underwater vehicles; however, they are highly nonlinear. It is extremely difficult to design control systems with nonlinear equations; therefore, the following highly successful, technique will be used. We will assume that a nominal flight path is given and design a controller to control the vehicle about the nominal flight path. The advantage of this approach is that the equations of motion describing small perturbations of the vehicle from its nominal flight path are linear. Furthermore, for many important flight paths, they are time invariant. The linearized equations of motion are derived by expanding both sides of (2.6) - (2.9) in Taylor's series, truncating each of the series after the linear terms, and evaluating the partial derivatives along the nominal flight path. Using the variational notation of Hildebrand[1], we can express the linearized equations as

$$\delta\dot{\vec{v}}^b = \delta C_\ell^b \, \vec{g}^\ell - \delta\vec{f}^b - \delta\vec{\omega}_{\ell b} \times \vec{v}^b_{nom} - \vec{\omega}_{\ell b_{nom}} \times \delta\vec{v}^b \tag{2.10}$$

$$I^b \delta\dot{\vec{\omega}}_{\ell b} = \delta M^b - \delta\vec{\omega}_{\ell b} \times I^b \vec{\omega}_{\ell b_{nom}} - \vec{\omega}_{\ell b_{nom}} \times I^b \delta\vec{\omega}_{\ell b} \tag{2.11}$$

$$\delta\dot{\vec{r}}^\ell = \delta C_b^\ell \, \vec{v}^b_{nom} + C^\ell_{b_{nom}} \, \delta\vec{v}^b \tag{2.12}$$

$$\delta\dot{C}^b_\ell = \delta C^b_\ell \left[\vec{\omega}_{\ell b_{nom}} \times\right] + C^b_{\ell_{nom}} \left[\delta\vec{\omega}^b_{\ell b} \times\right] \tag{2.13}$$

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1. F. B. Hildebrand, Methods of Applied Mathematics, Second Edition, Prentice-Hall, New Jersey, 1965, pp. 131-135.

where $\delta x(t)$ implies the first variation of $x(t)$, $\delta x(t) = x(t) - x^*(t)$ with $x^*(t)$ the nominal value of $x(t)$, and the subscript "nom" implies that the variable is evaluated along the nominal flight path. The first variation of a matrix X is simply a matrix whose components are the first variations of the components of X. We will further simplify (2.10)-(2.13) by limiting the nominal flight paths considered in this report to those for which

$$(\vec{\omega}^b_{\ell b})^T_{nom} \triangleq [P\ Q\ R]_{nom} = 0 \quad \text{(we have assumed a flat earth!)}$$

$$(\vec{v}^b)^T_{nom} \triangleq [U\ V\ W]^T_{nom} = [V_o\ 0\ 0]$$

$$C^b_{\ell_{nom}} = \text{Identity Matrix}$$

That is, we will consider nominal flight paths composed of only straight ahead motion at a constant speed, that speed can be zero. With these restrictions, (2.10)-(2.13) can be expressed as

$$\dot{\delta\vec{v}}^b = [\vec{g}^{\ell} \times]\delta\vec{\alpha} + [\vec{v}^b_{nom} \times]\delta\vec{\omega}^b_{\ell b} - \delta\vec{f}^b \tag{2.14}$$

$$\dot{\delta\vec{\omega}}^b_{\ell b} = (I^b)^{-1}\ \delta\vec{M}^b \tag{2.15}$$

$$\dot{\delta\vec{r}}^{\ell} = [\vec{v}^b_{nom} \times]\delta\vec{\alpha} + \delta\vec{v}^b \tag{2.16}$$

$$\dot{\delta\vec{\alpha}} = \delta\vec{\omega}^b_{\ell b} \tag{2.17}$$

where $\vec{\alpha}^T \triangleq [\Phi\ \Theta\ \Psi]$. In deriving (2.16) and (2.17), use was made of the observation that, for $\Phi^* = \Theta^* = \Psi^* = 0$, $\delta C^b_{\ell} = [\delta\vec{\alpha} \times]$.

2.4 Forces and Moments

The forces and moments acting on the vehicle are a result of gravity, propellers, bouyancy, and fluid flowing over the vehicle (in many cases modified by control surfaces). As was previously mentioned, the nominal values of these forces and moments, for a particular flight path, are in the initial local level frame; therefore, small perturbations in the vehicle's attitude, $\delta\vec{\alpha}$, will affect the actual forces and moments acting on the vehicle. The forces of propellers, bouyancy and gravity, and their resulting moments are easy to calculate, while the hydrodynamic forces (functions of the vehicle's shape, the currents, etc.) are more difficult to determine.

2.4.1 Gravity and Bouyancy

Because of the flat-earth assumption, gravity and bouyancy forces can be expressed as

$$\vec{g}^{\ell} = \begin{bmatrix} 0 \\ 0 \\ g \end{bmatrix} \qquad \vec{b}^{\ell} = \begin{bmatrix} 0 \\ 0 \\ -b \end{bmatrix} \tag{2.18,19}$$

Since gravity acts on the center-of-gravity of the vehicle, there is no resulting moment applied to the vehicle. The bouyancy force can be assumed to be applied at the center-of-bouyancy; therefore, it will cause a moment,

$$\vec{M}_b^b = C_{\ell}^{b}(\vec{r}_{\ell} \times \vec{b}^{\ell}) \tag{2.20}$$

(see Figure 2.2)

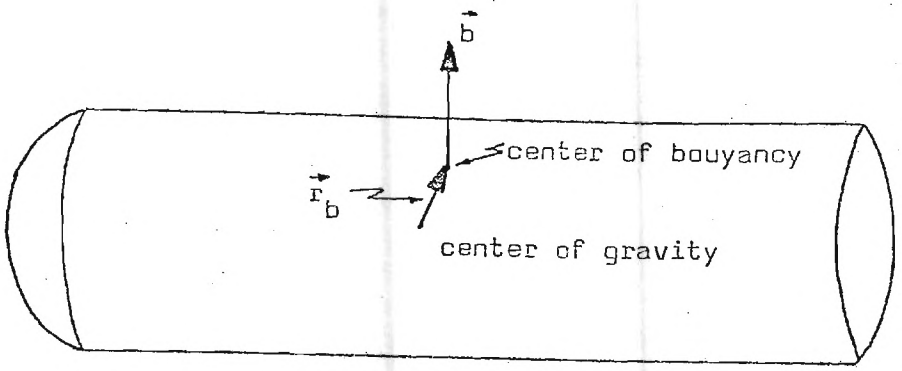

Figure 2.2 The bouyancy force and moment.

We determine the linearized nongravitational specific force resulting from the bouyancy by expanding (2.19) in a Taylor's series, which yields:

$$\left(\delta \vec{b}^{b}\right)^{T} = \begin{bmatrix} 0 \\ 0 \\ 1 \end{bmatrix} \delta b - \left[\vec{b}^{\ell} \times\right] \delta \underline{\alpha} \tag{2.21}$$

The linearized moment resulting from the bouyancy is determined in the same way with the series being truncated after the linear term and the partial derivatives evaluated along the nominal flight path. The results are:

$$\delta \vec{M}_b^b = \delta C_\ell^b \left(\vec{r}_b \times \vec{b}^{\ell}\right)\Big|_{nom} + \left(C_\ell^b\right)\Big|_{nom} \left(\vec{r}_b \times \delta \vec{b}^{\ell}\right) = 0 \tag{2.22}$$

In evaluating the partial derivatives in (2.22), it was assumed that, because of the symmetry of the mass of the vehicle, the vehicle's center of bouyancy is directly above its center of gravity--$\vec{r}_b$, $\vec{b}$ and $\delta \vec{b}^{\ell}$ are all collinear.

2.4.2 Propellers

We are interested in vehicles which use propellers for translating and/or attitude control. We will define the force resulting from the ith propeller as $\vec{F}_{P_i}$. The moment it produces can be expressed as

$$\vec{M}^{b}_{P_i} = C^{b}_{\ell}(\vec{r}^{\ell}_{P_i} \times \vec{F}^{\ell}_{P_i})$$

(see Figure 2.3)

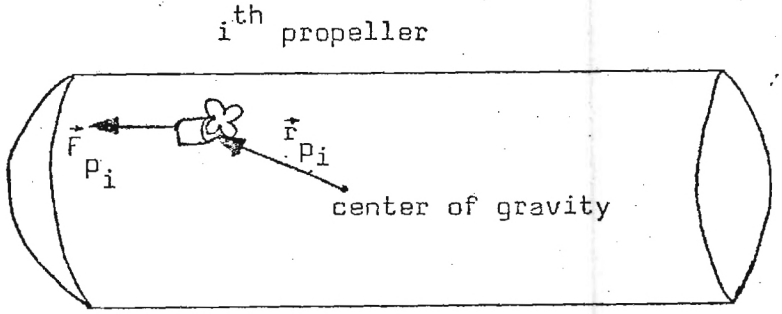

Figure 2.3. The propeller forces and moments.

Linearizing the propeller forces and moments yield $\delta \vec{F}^{b}_{p_i}$ and

$$\delta \vec{M}^{b}_{p_i} = \left[\vec{r}^{\ell}_{p_i} \times\right] \delta \vec{F}^{b}_{p_i} \tag{2.24}$$

where because $\vec{F}^{b}_{p_i}\Big|_{nom} = 0$, it follows that $\delta \vec{F}^{b}_{p_i} = \vec{F}^{b}_{p_i}$.

We will now specialize the vehicles considered to the ones which have four sets of propellers that produce

$$\delta \vec{F}^{b}_{p} = \begin{bmatrix} X_{\delta_{FA}} \\ 0 \\ 0 \end{bmatrix} \delta_{FA} + \begin{bmatrix} 0 \\ Y_{\delta_{BP}} \\ 0 \end{bmatrix} \delta_{BP} + \begin{bmatrix} 0 \\ Y_{SP} \\ 0 \end{bmatrix} \delta_{SP} + \begin{bmatrix} 0 \\ 0 \\ Z_{V} \end{bmatrix} \delta_{V} \tag{2.25}$$

$$\delta \vec{M}^{b}_{p} = \begin{bmatrix} L_{\delta_{BP}} \\ 0 \\ N_{\delta_{BP}} \end{bmatrix} \delta_{BP} + \begin{bmatrix} L_{\delta_{SP}} \\ 0 \\ N_{\delta_{SP}} \end{bmatrix} \delta_{SP} + \begin{bmatrix} 0 \\ M_{\delta_{FA}} \\ 0 \end{bmatrix} \delta_{FA} \tag{2.26}$$

where $X_{\delta_{FA}}$, $Y_{\delta_{BP}}$, Y_{SP}, and Z_{V} are the maximum forces produced by the fore and aft propellers, the bow propeller, the stern propeller, and the vertical propellers, respectively. In (2.25) the quantities δ_{FA}, δ_{BP}, δ_{SP} and δ_{V} are the normalized control variables and their values range from -1 to +1 depending upon the speed of the propeller and its direction of rotation. Equation (2.26) results from substituting each of the force vectors in (2.25) into (2.24) and summing up the results.

2.4.3 Hydrodynamic Forces and Moments

Because of the complexity involved, we will not derive closed form equations for the hydrodynamic forces and moments. We will simply note

that they are in general functions of the vehicle's translational acceleration and velocity, its altitude, angular velocity and angular acceleration, and the control surface's deflections.

$$\vec{F}_h^b = \vec{F}_h^b(\dot{\vec{v}}^b, \vec{v}^b, \vec{\alpha}, \vec{\omega}_{\ell b}^b, \dot{\vec{\omega}}_{\ell b}^b, \vec{\delta}) \tag{2.27}$$

$$\vec{M}_h^b = \vec{M}_h^b(\dot{\vec{v}}^b, \vec{v}^b, \vec{\alpha}, \vec{\omega}_{\ell b}^b, \dot{\vec{\omega}}_{\ell b}^b, \vec{\delta}) \tag{2.28}$$

Because the x,z plane of the vehicle is a plane of mass symmetry the hydrodynamic forces and moments can be expressed in the following functional forms

$$\vec{F}_h^b = C_\ell^b \begin{bmatrix} X_h(V,W,Q,\Theta,\dot{V},\dot{W},\dot{Q},\delta_B,\delta_S) \\ Y_h(V,P,R,\Phi,\psi,\dot{V},\dot{P},\dot{R},\delta_B,\delta_R) \\ Z_h(V,W,Q,\Theta,\dot{V},\dot{W},\dot{Q},\delta_B,\delta_S) \end{bmatrix} \tag{2.29}$$

and

$$\vec{M}_h^b = C_\ell^b \begin{bmatrix} L_h(V,P,R,\Phi,\psi,\dot{V},\dot{P},\dot{R},\delta_B,\delta_R) \\ M_h(V,W,Q,\Theta,\dot{V},\dot{W},\dot{Q},\delta_B,\delta_S) \\ N_h(V,P,R,\Phi,\psi,\dot{V},\dot{P},\dot{R},\delta_B,\delta_R) \end{bmatrix} \tag{2.30}$$

where the vehicles considered have been restricted to those which have a set of bow planes (δ_B), a set of stern planes (δ_S) and a rudder (δ_R) for control. We will further assume that the nominal values of the control surface deflections are zero. With these assumptions, the linearized force and moments resulting from the hydrodynamics can be expressed as

$$\delta\vec{F}_h^b = \begin{bmatrix} \frac{\partial X_h}{\partial x_{LO}} \\ 0 \\ \frac{\partial Z_h}{\partial x_{LO}} \end{bmatrix} x_{LO} + \begin{bmatrix} 0 \\ \frac{\partial Y_h}{\partial x_{LAT}} \\ 0 \end{bmatrix} x_{LAT} + \begin{bmatrix} \frac{\partial X_h}{\partial \delta_B} & \frac{\partial X_h}{\partial \delta_S} & 0 \\ \frac{\partial Y_h}{\partial \delta_B} & 0 & \frac{\partial Y_h}{\partial \delta_R} \\ \frac{\partial Z_h}{\partial \delta_B} & \frac{\partial Z_h}{\partial \delta_S} & 0 \end{bmatrix} \begin{bmatrix} \delta_B \\ \delta_S \\ \delta_R \end{bmatrix} \qquad (2.31)$$

and

$$\delta\vec{M}_h^b = \begin{bmatrix} \frac{\partial L_h}{\partial x_{LAT}} \\ 0 \\ \frac{\partial N_h}{\partial x_{LAT}} \end{bmatrix} x_{LAT} + \begin{bmatrix} 0 \\ \frac{\partial M_h}{\partial x_{LO}} \\ 0 \end{bmatrix} x_{LO} + \begin{bmatrix} \frac{\partial L_h}{\partial \delta_B} & 0 & \frac{\partial L_h}{\partial \delta_R} \\ \frac{\partial M_h}{\partial \delta_B} & \frac{\partial M_h}{\partial \delta_S} & 0 \\ \frac{\partial N_h}{\partial \delta_B} & 0 & \frac{\partial N_h}{\partial \delta_R} \end{bmatrix} \begin{bmatrix} \delta_B \\ \delta_S \\ \delta_R \end{bmatrix}$$

where the variables describing the vehicle's motion have been divided into the longitudinal variables

$$x_{LO}^T \triangleq [u, w, q, \theta, \dot{u}, \dot{w}, \dot{q}]$$

and the lateral variables

$$x_{LAT}^T \triangleq [v, p, r, \phi, \psi, \dot{v}, \dot{p}, \dot{r}]$$

and lower case letters are used to signify the first variation of a variable.

2.4.4 Linearized Equations of Motion

We are now in a position to express the linearized specific force in (2.14) and its resulting moment in

$$\delta\vec{f}^{b} = -\frac{1}{m}\begin{bmatrix}0\\0\\0\end{bmatrix}\delta b - \frac{1}{m}\begin{bmatrix}X_{\delta_{FA}}\\0\\0\end{bmatrix}\delta_{FA} - \frac{1}{m}\begin{bmatrix}0\\Y_{\delta_{BP}}\\0\end{bmatrix}\delta_{BP} - \frac{1}{m}\begin{bmatrix}0\\Y_{SP}\\0\end{bmatrix}\delta_{SP}$$

$$-\frac{1}{m}\begin{bmatrix}0\\0\\Z_V\end{bmatrix}\delta V - \frac{1}{m}\begin{bmatrix}\frac{X_h}{x_{LO}}\\0\\\frac{\partial Z_h}{\partial x_{LO}}\end{bmatrix}x_{LO} - \frac{1}{m}\begin{bmatrix}0\\\frac{\partial Y_h}{\partial x_{LAT}}\\0\end{bmatrix}x_{LAT}$$

$$-\frac{1}{m}\begin{bmatrix}\frac{\partial X_h}{\partial\delta_B} & \frac{\partial X_h}{\partial\delta_S} & 0\\ \frac{\partial Y_h}{\partial\delta_B} & 0 & \frac{\partial Y_h}{\partial\delta_R}\\ \frac{\partial Z_h}{\partial\delta_B} & \frac{\partial Z_h}{\partial\delta_S} & 0\end{bmatrix}\begin{bmatrix}\delta_B\\\delta_S\\\delta_R\end{bmatrix} \qquad (2.33)$$

and

$$\delta\vec{M}^{b} = \begin{bmatrix}L_{\delta_{BP}}\\0\\N_{\delta_{BP}}\end{bmatrix}\delta_{BP} + \begin{bmatrix}L_{\delta_{SP}}\\0\\N_{\delta_{SP}}\end{bmatrix}\delta_{SP} + \begin{bmatrix}0\\M_{\delta_{FA}}\\0\end{bmatrix}\delta_{FA}$$

$$+\begin{bmatrix}\frac{\partial L_h}{\partial x_{LAT}}\\0\\\frac{\partial N_h}{\partial x_{LAT}}\end{bmatrix}x_{LAT} + \begin{bmatrix}0\\\frac{\partial M_h}{\partial x_{LO}}\\0\end{bmatrix}x_{LO} + \begin{bmatrix}\frac{\partial L_h}{\partial\delta_B} & 0 & \frac{\partial L_h}{\partial\delta_R}\\ \frac{\partial M_h}{\partial\delta_B} & \frac{\partial M_h}{\partial\delta_S} & 0\\ \frac{\partial N_h}{\partial\delta_B} & 0 & \frac{\partial N_h}{\partial\delta_R}\end{bmatrix}\begin{bmatrix}\delta_B\\\delta_S\\\delta_R\end{bmatrix} \qquad (2.34)$$

Substituting (2.33) and (2.34) into (2.14) and (2.15) and performing a little algebra yields:

- Longitudinal -

$$P_{LO}\begin{bmatrix}\dot{u}\\ \dot{w}\\ \dot{q}\\ \dot{\theta}\end{bmatrix} = A_{LO}\begin{bmatrix}u\\ w\\ q\\ \theta\end{bmatrix} + B_{LO}\begin{bmatrix}\delta_{FA}\\ \delta_{V}\\ \delta_{B}\\ \delta_{S}\end{bmatrix} + \begin{bmatrix}0\\ -1\\ 0\\ 0\end{bmatrix}\delta b \tag{2.35}$$

$$\dot{x}_0 = u \tag{2.36}$$

$$\dot{z}_0 = V_0\,\theta + w \tag{2.37}$$

- Lateral -

$$P_{LAT}\begin{bmatrix}\dot{v}\\ \dot{p}\\ \dot{r}\\ \dot{\phi}\\ \dot{\psi}\end{bmatrix} = A_{LAT}\begin{bmatrix}v\\ p\\ r\\ \phi\\ \psi\end{bmatrix} + B_{LAT}\begin{bmatrix}\delta_{BP}\\ \delta_{SP}\\ \delta_{B}\\ \delta_{R}\end{bmatrix} \tag{2.38}$$

$$\dot{y}_0 = -\,V_0\,\psi + v \tag{2.39}$$

where the matrices P_{LO}, A_{LO}, B_{LO}, P_{LAT}, A_{LAT} and B_{LAT} are defined in Appendix A.

3. Available Measurements

3.1 Accelerometers

The accelerometers measure the[1] "nonfield specific force which the instruments exert on the support." The nonfield specific force at the instrument package is given by[2]

$$\vec{f}_p = \vec{g} - p_\ell^2 \vec{r} + p_\ell \vec{\omega}_{\ell b} \times \vec{r}_p + \vec{\omega}_{\ell b} \times (\vec{\omega}_{\ell b} \times \vec{r}_p) \tag{3.1}$$

where $\vec{r}_p$ is the position of the instrument package with respect to the CG. Substituting (2.2) into (3.1) yields:

$$\vec{f}_p^b = \vec{f}^b + \dot{\vec{\omega}}_{\ell b} \times \vec{r}_p^b + \vec{\omega}_{\ell b} \times (\vec{\omega}_{\ell b} \times \vec{r}_p^b) \tag{3.2}$$

Expanding both sides of (3.2) in a Taylor's series, truncating the series after the linear term, and evaluating the partial derivatives along the nominal flight path yields:

$$\delta\vec{f}_p^b = \delta\vec{f}^b - \vec{r}_p \times \delta\dot{\vec{\omega}}_{\ell b}^b \tag{3.3}$$

where, since $|\vec{r}_p|$ is of the same size as $|\delta\vec{r}|$, the term $[\vec{r}_p \times]\delta\vec{\omega}_{\ell b}^b$ is considered to be second order and neglected. Therefore, if we process the measurements as is shown in Figure 3.1, then the linearized accelerometer measurement is

$$\vec{m}_a = \delta\vec{f}^b + \vec{n}_a \tag{3.4}$$

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1. Wrigley, op.cit., p. 51
2. Wrigley, ibid., p. 245

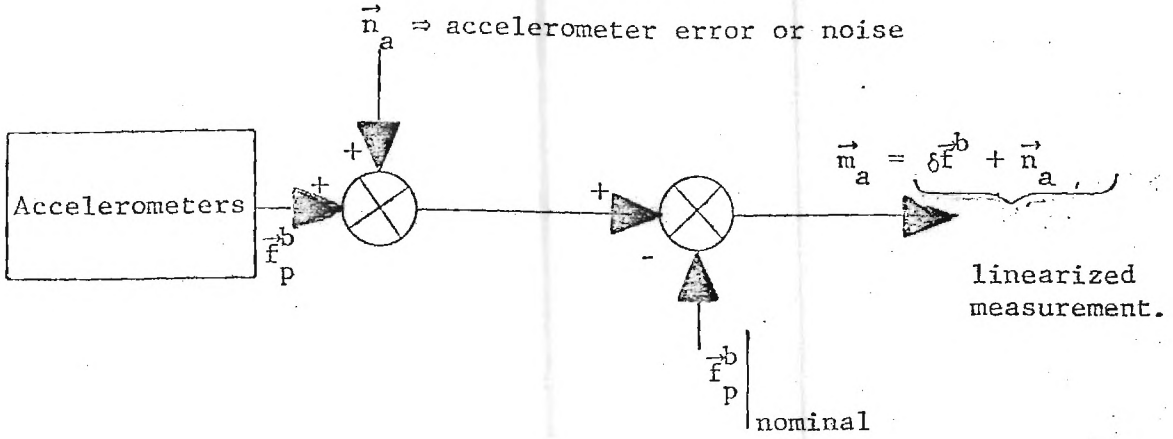


Figure 3.1 The linearized accelerometer measurement.

3.2 Gyros

The gyros measure the angular velocity of the vehicle with respect to the initial local level frame. If we process the measurements as is shown in Figure 3.2, then the linearized gyro measurement is

$$\vec{m}_g = \delta\vec{\omega}^b_{\ell b} + \vec{n}_g \tag{3.5}$$

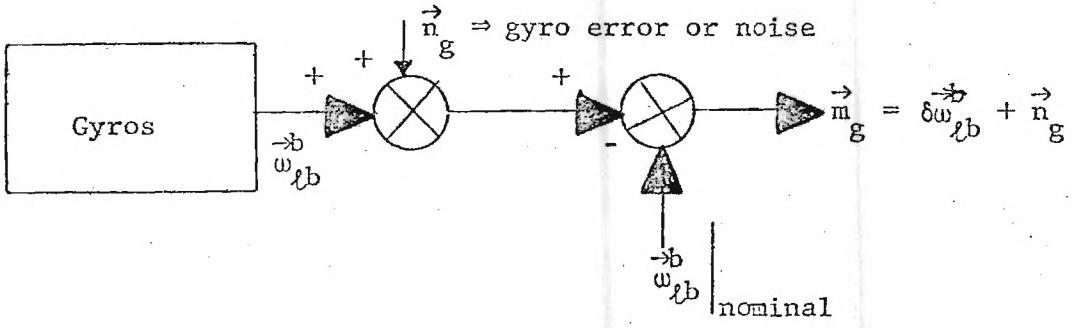


Figure 3.2 The linearized gyro measurement.

3.3 Position Measurements

The position measurements to be considered are reference points in the bay. The initial position of the vehicle will be surveyed and well known. We will also survey several reference points and identify them so that the vehicle can pass over the references (see Figure 3.3).

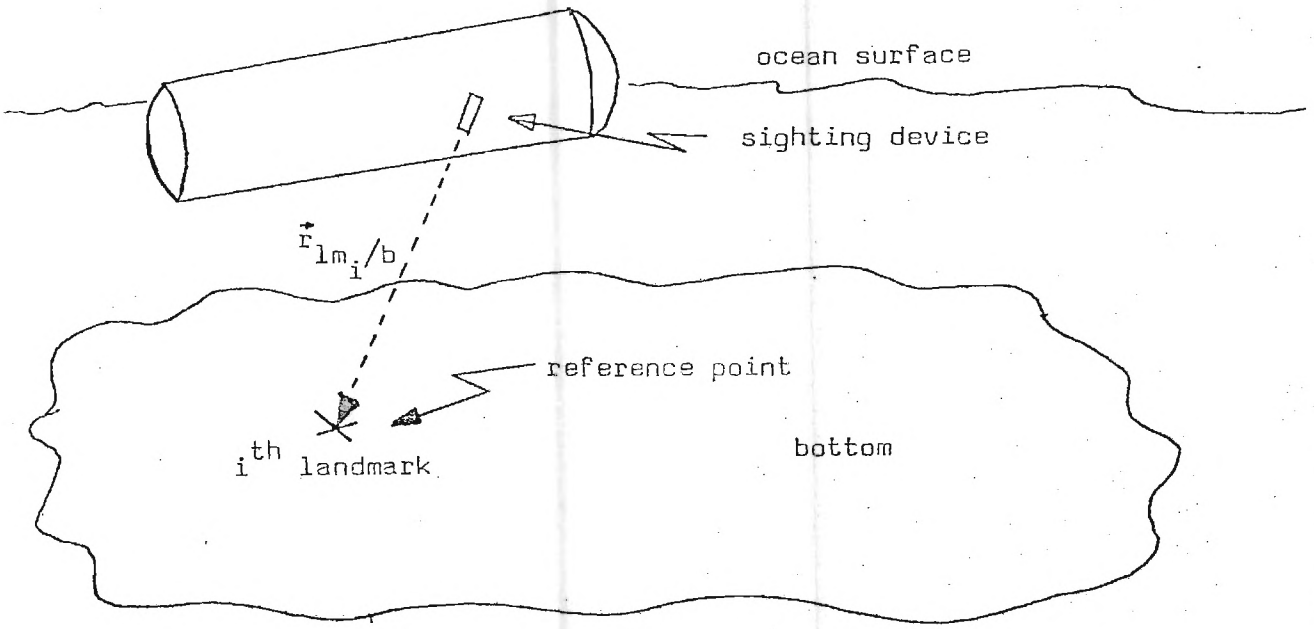


Figure 3.3 Landmark sightings.

When the nominal flight path calls for the vehicle to be over the known landmark, we use the sighting device to determine a unit vector along $\vec{r}_{\ell m_i/b}$

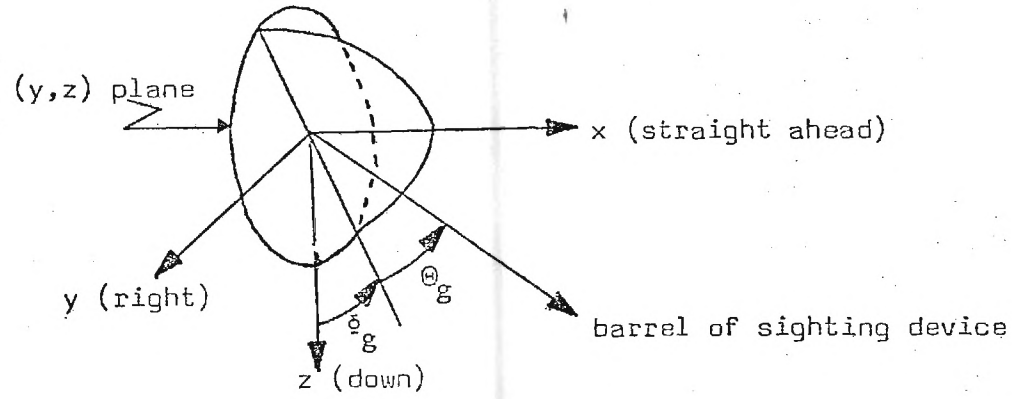


Figure 3.4 Geometry of sighting device.

An examination of Figure 3.4 shows that once the sighting device is pointed at the landmark, we can determine a unit vector along $\vec{r}_{\ell m_i/b}$ from the sighting device's gimbal angles ($\bar{o}_g$ and Θ_g).

$$\hat{u}^{\ell}_{\ell m_i} \triangleq \left(\frac{\vec{r}_{\ell m_i|b}}{|\vec{r}_{\ell m_i|b}|}\right)^{\ell} = C^{\ell}_{b} \begin{bmatrix} S\Theta_{g_i} \\ -C\Theta_{g_i} S\bar{\Phi}_{g_i} \\ C\Theta_{g_i} C\bar{\Phi}_{g_i} \end{bmatrix} \tag{3.6}$$

Expanding both sides of (3.6) in a Taylor's series, truncating the series after the linear terms, and evaluating the partial derivatives along the nominal flight path yields:

$$\delta\hat{u}^{\ell}_{\ell m_i} = \begin{bmatrix} \theta_{g_i} \\ -\varphi_{g_i} \\ 0 \end{bmatrix} + \left\{ \begin{bmatrix} 0 \\ 0 \\ 1 \end{bmatrix} \times \delta\vec{\alpha} \right\} = \begin{bmatrix} \theta_{g_i} - \theta \\ \varphi - \varphi_{g_i} \\ 0 \end{bmatrix} \tag{3.7}$$

where $\theta_{g_i} = \Theta_{g_i} - \Theta^{*}_{g_i}$, $\varphi_{g_i} = \bar{\Phi}_{g_i} - \bar{\Phi}^{*}_{g_i}$, $\theta = \Theta - \Theta^{*}$, $\varphi = \bar{\Phi} - \bar{\Phi}^{*}$, and the nominal gimbal angles have been assumed to be 0°. The assumption of 0° for the nominal gimbal angles corresponds to the vehicle being directly over the landmark. We can also express the landmark unit vector as

$$\hat{u}^{\ell}_{\ell m_i} = \frac{\vec{r}_{\ell m_i|\ell\ell} - \vec{r}^{\ell}}{|\vec{r}^{\ell}_{\ell m_i|\ell\ell} - \vec{r}^{\ell}|} \tag{3.8}$$

where $\vec{r}_{\ell m_i|\ell\ell}$ is the position vector of the known landmark with respect to the initial local level frame (this is determined from surveying). Expanding both sides of (3.8) in a Taylor's series truncating the series after the linear terms, and evaluating the partial derivatives along the nominal flight path yields:

$$\delta\hat{u}^{\ell}_{\ell m_i} = LM_i \, \delta\vec{r} \tag{3.9}$$

where

1) $LM_i = \frac{1}{d_i}\left[I - \frac{\vec{d}_i \vec{d}_i^{T}}{d_i^2}\right]$ is the projection operator. After a vector is multiplied by LM_i, the result is the negative of the component of the vector orthogonal to $\vec{d}_i$ divided by d_i.

2) I is the identity matrix

3) $\vec{d}_i = [0\ 0\ d_i]$ is the depth vector of the ith landmark and d_i is the depth of the ith landmark.

Combining (3.7) and (3.8) yields:

$$\begin{bmatrix} \theta_{g_i} - \theta \\ \varphi - \varphi_{g_i} \end{bmatrix} = - \begin{bmatrix} \delta r_x \\ \delta r_y \end{bmatrix} / d_i$$

or

$$\begin{bmatrix} \theta_{g_i} \\ \varphi_{g_i} \end{bmatrix} = H_{\ell m_i} \begin{bmatrix} \vec{\delta r}^{\ell} \\ \vec{\delta \alpha}^{\ell} \end{bmatrix}$$

where $H_{\ell m_i} = \begin{bmatrix} -\frac{1}{d_i} & 0 & 0 & 0 & 1 & 0 \\ 0 & \frac{1}{d_i} & 0 & 1 & 0 & -0 \end{bmatrix}$

Therefore, if we process the sighting device's gimbal angles, as is shown in Figure 3.5, we can express the linearized measurement as

$$\vec{m}_{\ell m_i} = H_{\ell m_i} \begin{bmatrix} \vec{\delta r}^{\ell} \\ \vec{\delta \alpha} \end{bmatrix} + \vec{n}_{\ell m_i} \qquad (3.10)$$

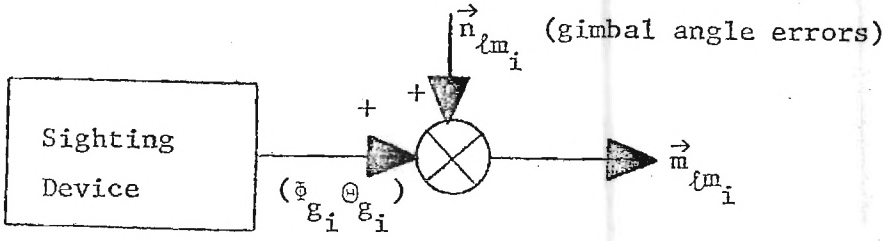


Figure 3.5 The linearized landmark measurement.

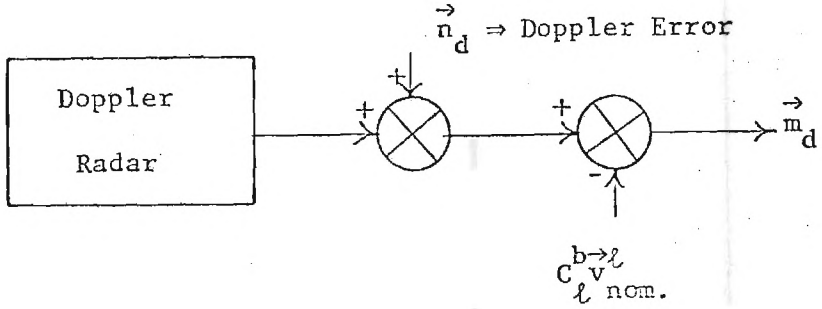
3.4 Doppler Measurements

We will consider the Doppler radar measurements to indicate the velocity of the craft with respect to the initial local level frame coordinatized in the body frame. This implies the assumptions that the radar antennas are fixed to the craft and the error in the transformation from the radar antenna coordinate system to the body coordinate system is negligible. Subject to these assumptions, we can express the Doppler radar measurement as[1]

$$\vec{m}_d = \vec{v}^b + \vec{n}_d \tag{3.11}$$

where $\vec{n}_d$ is the error associated with the radar measurement. If we process the measurement as is shown in Figure 3.6, we can express the linearized measurement as

$$\vec{m}_d = \delta\vec{v}^b - [\vec{v}^{\ell}_{nom} \times]\delta\vec{\alpha} + \vec{n}_d \tag{3.12}$$



1. M. Kayton and W. R. Fried, Avionics Navigation Systems, Wiley, 769, pp.211.

4.0 Navigation

In this work, we will consider the gyros and accelerometers as the basic navigation measurements. The other available measurements--Doppler radar, etc.--will be used to correct the errors in the basic navigation system's output and to remove instrument errors.

These are basically two ways to use the gyro and accelerometer measurements. To see these and to understand why one is perferable to the other consider the following. We will ignore the problem of coordinate systems, Coriolis effects, etc., in order to simplify the argument and make the ideas clear. We begin with Newton's law

$$\underline{F}/m = \underline{a} \tag{4.1}$$

and immediately observe that the force $\underline{F}$ acting on the vehicle is a rather complicated function of both the velocity and the acceleration of the craft. Not only is this functional relationship rather complicated, it is precisely what we are trying to identify. On the other hand, the acceleration $\underline{a}$ is just a kinematical relationship and well known. Finally, we observe that the specific force measured by the accelerometer is

$$\underline{f} = \underline{a} - \underline{g} \tag{4.2}$$

or

$$\underline{f} + \underline{g} = \underline{a} \tag{4.3}$$

where $\underline{g}$ is the gravity vector. At this point it becomes clear that we can use either (4.1) or (4.3) as the equations of linear motion; however, by using (4.3), we eliminate the complicated and unknown force terms $\underline{F}$--they are replaced by the accelerometer measurements. As is always the case, a price

is paid for this simplification--we have thrown away all of the information we have about the inputs to the craft and the functional relationship between the accelerations and velocities and the forces acting on the vehicle.

In summary, the two basic navigational modes for the systems we are considering are:

1. From the functional relationships between the forces and the accelerations, the velocities, and the inputs, evaluate the left-hand side of (4.1) and set it equal to the acceleration of the craft. Integrate the acceleration once to determine the craft's velocity and again to determine its position.

2. Add gravity to the outputs of the accelerometers to obtain the craft's acceleration. Integrate the acceleration once to determine the craft's velocity and again to determine its position.

In the beginning we definitely prefer the second method. Not only are the functional relationships unknown, it's rather hard to know the inputs--ocean swells and currents and wind gusts. However, since we are performing the system's identification off-line, we can make several passes at the data. After we have roughly identified the vehicle's parameters, we will use both methods simultaneously and combine their estimates via an extended Kalman filter algorithm. The combined estimates will then be used to better identify the system parameters, and the procedure will be repeated until no improvement results.

The other measurements available for navigation will be incorporated into the estimates of the craft's state and the instrument errors via the extended Kalman filter algorithm yielding an aided-navigation mode.

One other bit of information has been used to estimate the initial alignment of the vehicle. When the craft is stationary, (4.2) reduces to

$$\underline{f} = -\underline{g} \tag{4.4}$$

It will be shown that, if we consider which coordinate system the measurements are made in and the coordinate system we know gravity in, (4.4) yields:

$$\begin{bmatrix} f_x \\ f_y \end{bmatrix} = \begin{bmatrix} 0 & -g \\ g & 0 \end{bmatrix} \begin{bmatrix} \phi \\ \theta \end{bmatrix} + \text{noise} \tag{4.5}$$

where the noise is the sum of the unknown inputs to the vehicle and accelerometer noise, and ϕ and θ are the vehicle's roll and pitch angles. Equation (4.5) will be used with a prefiltering version of the Kalman filter to estimate the initial alignment of the craft.

4.1 Alignment Mode

During the alignment mode, we will take advantage of the fact that the vehicle is stationary (except for wave motion, wind gusts, etc.) to determine the vehicle's initial attitude. For the stationary case, (2.14) can be rewritten as

$$[\vec{g}^{\ell} \times]\delta\vec{\alpha} = \delta\vec{f}^{b} + \delta\dot{\vec{v}}^{b} \tag{4.6}$$

or

$$\theta = -\delta f_x/g - \dot{u}/g \tag{4.7}$$

$$\phi = \delta f_y/g + \dot{v}/g \tag{4.8}$$

where $\delta\vec{f}^{b} = [\delta f_x \ \delta f_y \ \delta f_z]^T$ and $\delta\vec{v}^{b} = [u \ v \ w]^T$. Substituting the linearized accelerometer measurements into (4.6)-(4.8) yields:

$$\begin{bmatrix} \delta f_x \\ \delta f_y \end{bmatrix} = H_1 \begin{bmatrix} \phi \\ \theta \end{bmatrix} + \underline{n}_1 \tag{4.9}$$

where

$$H_1 = \begin{bmatrix} 0 & -g \\ g & 0 \end{bmatrix} \qquad n_1 = \begin{bmatrix} -\dot{u} \\ -\dot{v} \end{bmatrix} + \begin{bmatrix} n_{ax} \\ n_{ay} \end{bmatrix}$$

Observe that the noise term in (4.9) is the weighted sum of the accelerometer errors and the small perturbations in the vehicle's linear accelerations. We will consider the noises and accelerations to be Gaussian random processes with zero mean values and statistically independent from one sample to the next. We will define

$$R_1 = \text{cov}[\underline{n}_1, \underline{n}_1]$$

where $\text{cov}[\underline{n}_1, \underline{n}_1] \triangleq E\{[\underline{n}_1 - E\{\underline{n}_1\}][\underline{n}_1 - E\{\underline{n}_1\}]^T\}$, and use the prefiltering version of the Kalman filter[1],[2],[3] to estimate the initial values of θ and φ. We preprocess the measurements via

$$\tilde{m}(N) = H_1^T R_1^{-1} \sum_{i=1}^{N} \begin{bmatrix} \delta f_x \\ \delta f_y \end{bmatrix}_i \tag{4.10}$$

$$\tilde{J}(N) = N H_1^T R_1^{-1} H_1 \tag{4.11}$$

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1. Fourth Quarterly Progress Report, Contract NAS0-10386, MIT Draper Laboratory, Cambridge, Mass., April 30, 1971.
2. M. E. Womble, "The Linear-Quadratic-Gaussian Problem with Ill-Conditional Riccati Matrices," Ph.D. Thesis, Dept. of Aero. and Astro., MIT, Cambridge, Mass., May, 1972.
3. M. E. Womble and J. E. Potter, "A Prefiltering Version of the Kalman Filter with New Integration Formulas for Ricati Equations," Proceedings of the 1973 IEEE Conference on Division and Control. To appear in the IEEE Trans. on Auto. Control.

and estimate the angles and the error via

$$P = [I + P_0 \tilde{J}(N)]^{-1} P_0 \tag{4.12}$$

$$\begin{bmatrix} \hat{\varphi} \\ \hat{\theta} \end{bmatrix} = [I - P\tilde{J}] \begin{bmatrix} \hat{\varphi}_0 \\ \hat{\theta}_0 \end{bmatrix} + P\tilde{M}(N) \tag{4.13}$$

4.2 Basic Navigation Mode

Once the vehicle becomes propelled we will use the accelerometer and gyro measurements as the basic inputs for navigation. Other measurements will be used as aids. In the basic mode, we will use the corrected output of the accelerometers and gyros to determine estimates of $\delta\vec{\omega}^{b}_{\ell b}$ and $\delta\vec{f}^{b}$ in (2.14) and (2.17). Substituting (3.4) and (3.5) into (2.14) and (2.17) yields:

$$\dot{\delta\vec{v}}^{b} = [\vec{g}^{\ell} \times] \ \vec{\delta\alpha} + [\vec{v}^{b}_{nom} \times] \ [\vec{m}_g - \vec{n}_g] - \vec{m}_a + \vec{n}_a \tag{4.14}$$

and

$$\dot{\vec{\delta\alpha}} = \vec{m}_g - \vec{n}_g \tag{4.15}$$

Therefore, the basic navigation equations to be used are

$$\dot{\tilde{\underline{x}}} = \tilde{A}\,\tilde{\underline{x}} + \tilde{B}\,\tilde{\underline{u}} \tag{4.16}$$

where

$$\tilde{\underline{x}}^T = [(\delta\vec{v}^{b})^T (\delta\vec{r}^{\ell})^T \ \vec{\delta\alpha}^T] \qquad \tilde{\underline{u}}^T = [\tilde{m}^T \ \tilde{m}_g^T]$$

$$\tilde{A} = \begin{bmatrix} 0^{3x3} & 0^{3x3} & [\vec{g}^{\ell} \times] \\ I^{3x3} & 0^{3x3} & [\vec{v}^{b}_{nom} \times] \\ 0^{3x3} & 0^{3x3} & 0^{3x3} \end{bmatrix} \qquad \tilde{B} = \begin{bmatrix} -I^{3x3} & [\vec{v}^{b}_{nom} \times] \\ 0^{3x3} & 0^{3x3} \\ 0^{3x3} & I^{3x3} \end{bmatrix}$$

Observe that in using (4.16), we are assuming that all the noises are zero. Since we do not accurately know the vehicle's dynamics, this is the best we can do with only accelerometer and gyro measurements.

5. Identification

The purpose of this task is to develop an algorithm to identify from flight test data an accurate model of water vehicles. First several existing techniques will be investigated.

5.1 Taylor and Iliff's Method[1]

This method falls into the class of identification techniques known as[2] "output error methods," techniques which adjust the model parameter to make the measurements predicted by the model closely match the actual measurements. This class of techniques does not consider perturbations in the inputs (i.e. perturbations in the ocean currents, etc.); therefore, their best performance will be when the flight tests are performed under conditions as near as possible to ideal. In this method, we assume that the unknown system dynamics can be expressed as

$$\dot{\underline{x}} = A\,\underline{x} + B\,\underline{u} \tag{5.1}$$

$$\underline{y} = F\,\underline{x} + G\,\underline{u} + \underline{b} \tag{5.2}$$

$$\underline{z} = \underline{y} + \underline{n} \tag{5.3}$$

where y is the part of the measurement z caused by the system and $\underline{n}$ is the measurement noise. The vector $\underline{b}$ in (5.2) represents biases -- for instance we will use this to represent gyro drifts, accelerometer biases, etc. All vectors and matrices in (5.1) and (5.2) are considered to be functions of the vector $\underline{c}$, whose components are the unknown parameters. The idea behind this

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1. L. W. Taylor and K. W. Iliff, "Systems Identification Using a Modified Newton-Raphson Method - A Fortran Program," NASA TN D-6734, May 1972.
2. R. K. Mehra and J. S. Tyler, "Case Studies in Aircraft Parameter Studies," Proceedings of the Third IFAC Symposium on Identification and System Parameter Estimation, The Hague/Delft, The Netherlands, June 1973.

method is to determine the parameter vector $\underline{c}$ which minimizes the least square error cost function

$$J = \frac{1}{2} \sum_{i=1}^{N} (z_i - y_i)^T D_1 (z_i - y_i) \tag{5.4}$$

where D_1 is required to be a symmetric positive definite matrix and N is the number of measurements made. Observe, that in (5.4), we are trying to drive the predicted measurements y_i close to the actual measurements z_i. The matrix D_1 is the means of considering the measurement noise $\underline{n}$ -- the larger the noise, the smaller we make D_1.

The particular optimization technique used is a Newton-Raphson method. It is based on determining the value of $\underline{c}$ which will make $\partial J/\partial \underline{c} = 0$. Observe that this is a necessary condition for $\underline{c}$ to minimize J. Expanding $\partial J/\partial \underline{c}$ in a Taylor's series yields:

$$\frac{\partial J}{\partial \underline{c}} = \frac{\partial J}{\partial \underline{c}}\bigg|_{\underline{c}=\underline{c}_0} + (\underline{c} - \underline{c}_0)^T \left.\frac{\partial^2 J}{\partial \underline{c}^2}\right|_{\underline{c}=\underline{c}_0} + (\text{HOT}) \tag{5.5}$$

where HOT are the higher order terms, and $\underline{c}_0$ is our present best guess of $\underline{c}$. From (5.5), we see that the value of $\underline{c}$ we want satisfies

$$(\underline{c} - \underline{c}_0)^T = -\left\{\frac{\partial J}{\partial \underline{c}} \left[\frac{\partial^2 J}{\partial \underline{c}^2}\right]^{-1}\right\}\bigg|_{c=c_0}$$

or

$$\underline{c} = \underline{c}_0 - \left\{\left[\frac{\partial^2 J}{\partial \underline{c}^2}\right]^{-1} \left(\frac{\partial J}{\partial \underline{c}}\right)^T\right\}\bigg|_{c=c_0} \tag{5.6}$$

We obtain the partial derivatives required in (5.7) as follows. Differentiating (5.4) yields:

$$\frac{\partial J}{\partial \underline{c}} = \sum_{i=1}^{N} (y_i - \underline{z}_i)^T D_1 \frac{\partial \underline{y}_1}{\partial \underline{c}} \tag{5.7}$$

Differentiating (5.7) yields:

$$\frac{\partial^2 J}{\partial \underline{c}^2} = \frac{\partial}{\partial \underline{c}} \left[\frac{\partial J}{\partial \underline{c}}\right]^T = \sum_{i=1}^{N} \left(\frac{\partial \underline{y}_i}{\partial \underline{c}}\right)^T D_1 \frac{\partial \underline{y}_i}{\partial \underline{c}}$$

$$+ \sum_{i=1}^{N} (\underline{y}_i - \underline{z}_i)^T D_1 \frac{\partial^2 \underline{y}_i}{\partial \partial^2 \underline{c}} \qquad (5.8)$$

where $\frac{\partial^2 \underline{y}_i}{\partial \underline{c}}$ remains to be defined. Observe that when $\underline{c} \to c_0$, $|(\underline{y}_i - \underline{z}_i)|$; $i = 1, \ldots, N$ will be a small term; therefore, in (5.6) we will consider

$$(\underline{c} - \underline{c}_0)^T \sum_{i=1}^{N} (\underline{y}_i - \underline{z}_i)^T D_1 \frac{\partial^2 \underline{y}_i}{\partial^2 \underline{c}^2}$$

to be a second order term. Substituting what is left of (5.8), and (5.7) into (5.6) yields:

$$\underline{c} = \underline{c}_0 + \left[\sum_{i=1}^{N} \left(\frac{\partial \underline{y}_i}{\partial \underline{c}_0}\right)^T D_1 \frac{\partial \underline{y}_i}{\partial c_0}\right]^{-1} \sum_{i=1}^{N} \left(\frac{\partial \underline{y}_i}{\partial \underline{c}_0}\right)^T D_1 \left[z_i - \underline{y}_i(\underline{c}_0)\right] \qquad (5.9)$$

which is the iterative algorithm used. The iteration is to enter a guess $\underline{c}_0$ into (5.9) to get a better estimate of $\underline{c}$. The procedure is repeated until a value of $\underline{c}$ is found for which $|\underline{c} - \underline{c}_0|$ is insignificant. Observe that once $\underline{c}_0$ is specified, $\underline{y}_i(\underline{c}_0)$ can be determined directly from (5.1) and (5.2); however, the gradient vector, $\partial \underline{y}_i / \partial \underline{c}_0$, is a little more difficult to determine. First we differentiate both (5.1) and (5.2) with respect to $\underline{c}$, which yields

$$\frac{d}{dt}\left[\frac{\partial \underline{x}}{\partial \underline{c}}\right] = \frac{\partial A}{\partial \underline{c}} \underline{x} + A \frac{\partial \underline{x}}{\partial \underline{c}} \qquad (5.10)$$

and

$$\frac{\partial \underline{y}}{\partial \underline{c}} = F \frac{\partial \underline{x}}{\partial \underline{c}} + \frac{\partial F}{\partial \underline{c}} \underline{x} + \frac{\partial G}{\partial \underline{c}} \underline{u} + G \frac{\partial \underline{u}}{\partial \underline{c}} + \frac{\partial \underline{b}}{\partial \underline{c}} \qquad (5.11)$$

where the operation of multiplying the derivative of a matrix with respect to a vector by another vector is defined as:

$$\frac{\partial \underline{X}}{\partial \underline{c}}\,\underline{x} \Rightarrow \left[\frac{\partial \underline{X}}{\partial \underline{c}}\,\underline{x}\right]_{ij} \triangleq \sum_{j=1}^{m} \frac{\partial x_{ij}}{\partial \underline{c}}\, x_j$$

with $\underline{x}$ a (k x 1) vector and X a (m x k) matrix. Therefore, we obtain $\partial \underline{y}/\partial \underline{c}$ from (5.10) and (5.11).

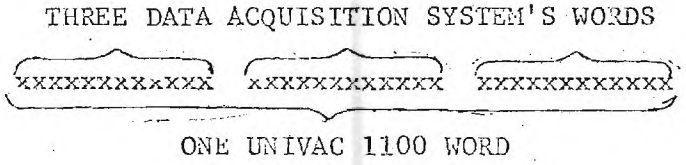
6. Results

The ultimate objective of this study is to develop algorithms capable of extracting the desired transfer functions from flight-test data. This task which is merely the first step involves 1) developing the capability of processing flight test data recorded on magnetic tape, 2) developing navigation algorithms for smoothing the data and producing estimates of the state of the craft, and 3) putting existing identification algorithms by Taylor on the Georgia Tech Univac 1100 computer and verifying that they work.

6.1 Data Processing

The data received from NCSL consisted of the outputs of three strap-down gyros and accelerometers sampled every 0.02 seconds. These six signals are recorded on seven-track magnetic tape in records of forty samples. The tape is written in the form of files, each file corresponding to a particular maneuver and consisting of a specified number of records. On the tapes received at Georgia Tech (#1479 and #1856), each data file is preceded by a file which contains information about the following data file.

The first step in getting the data into a form useable in the Univac 1100 computer is a result of the difference in word length between the data acquisition system and the Univac 1100. The data acquisition system which writes the tape uses a twelve bit wordlength while the Univac 1100 uses a 36 bit wordlength. Therefore, when the Univac reads one word off the tape, it is actually reading three of the data acquisition system's words.



As a result, the first step in processing the data read from the magnetic tape is to break each word read into three words.

The outputs recorded on the tape are the number of pulses received from the gyros and accelerometers between samples (.02 seconds). The scalings used to convert the data to (radians/sec.) and (ft./sec.^{2}) are

$$w_x = (x_1 - 640)\ (7.622078645E\text{-}04)$$
$$w_y = (640 - x_2)\ (7.613280004E\text{-}04)$$
$$w_z = (640 - x_3)\ (7.631259562E\text{-}04)$$
$$f_x = (x_4 - 640)\ (\ .1563082025)$$
$$f_y = (640 - x_5)\ (\ .156280745)$$
$$f_z = (640 - x_6)\ (\ .1556946525)$$

where $x_1, x_2, \ldots, x_6$ are the numbers from the magnetic tape, $\underline{w}^T = [w_x, w_y, w_z]$ is the angular velocity, and $\underline{f}^T = [f_x, f_y, f_z]$ is the specific force--$(\underline{a} - \underline{g})$.

After the data is scaled, it is written into a datafile on the F2 drum in the Univac system. The data is written into the file in the form of records, each record consisting of 40 samples of 6 words each (3 angular rates and 3 specific forces).

Plots of the angular rates and the specific forces obtained from the 6th file on tape #1479 are shown in Figures 6.1 and 6.2. The time increment used in making the plots is 2 seconds, and the first point plotted is the 100th sample in the file (this is defined as t=2 seconds).

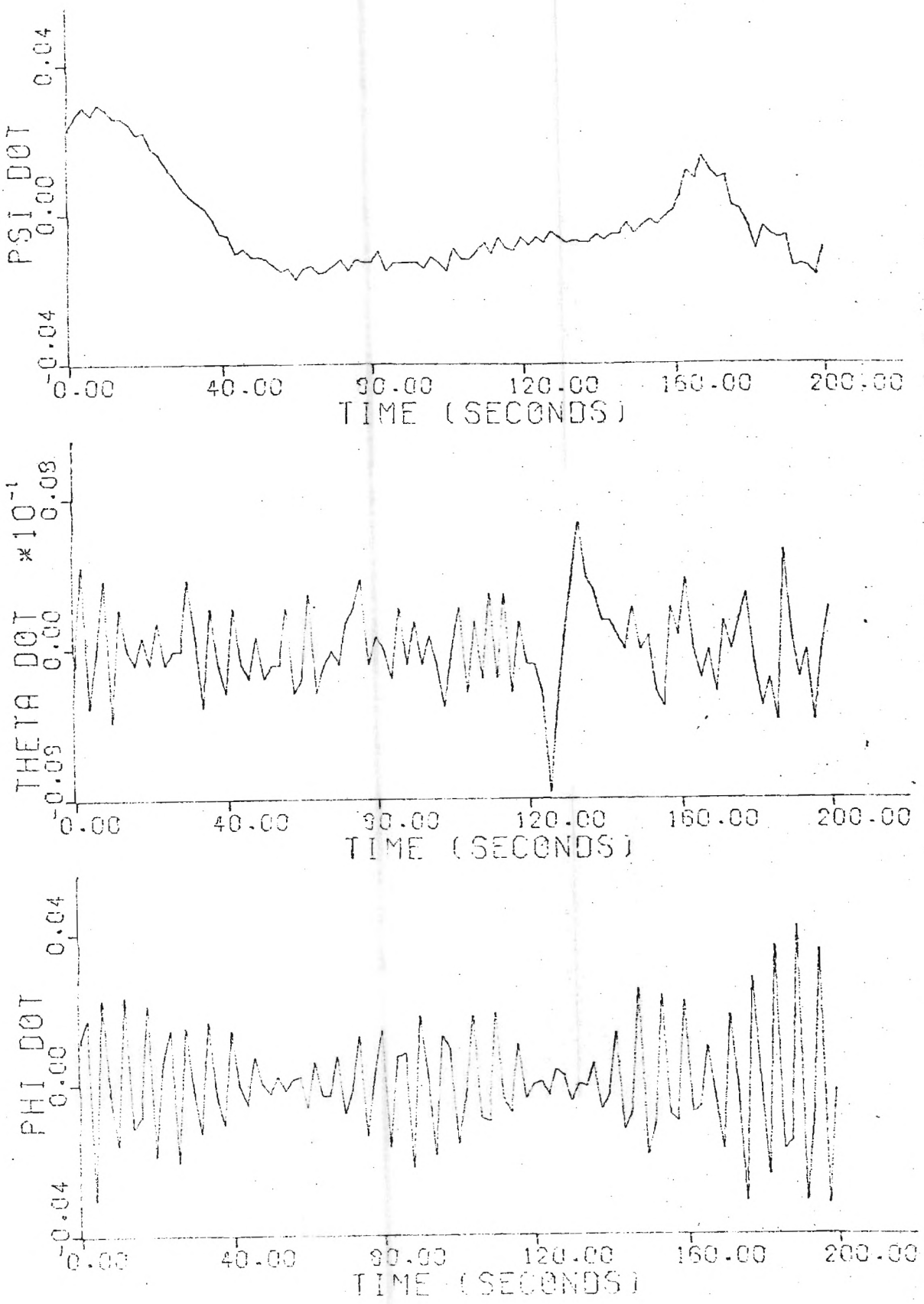


Figure 6.1 The Angular Rates in Radians/sec. Obtained from File No. 5 of Tape No. 1479

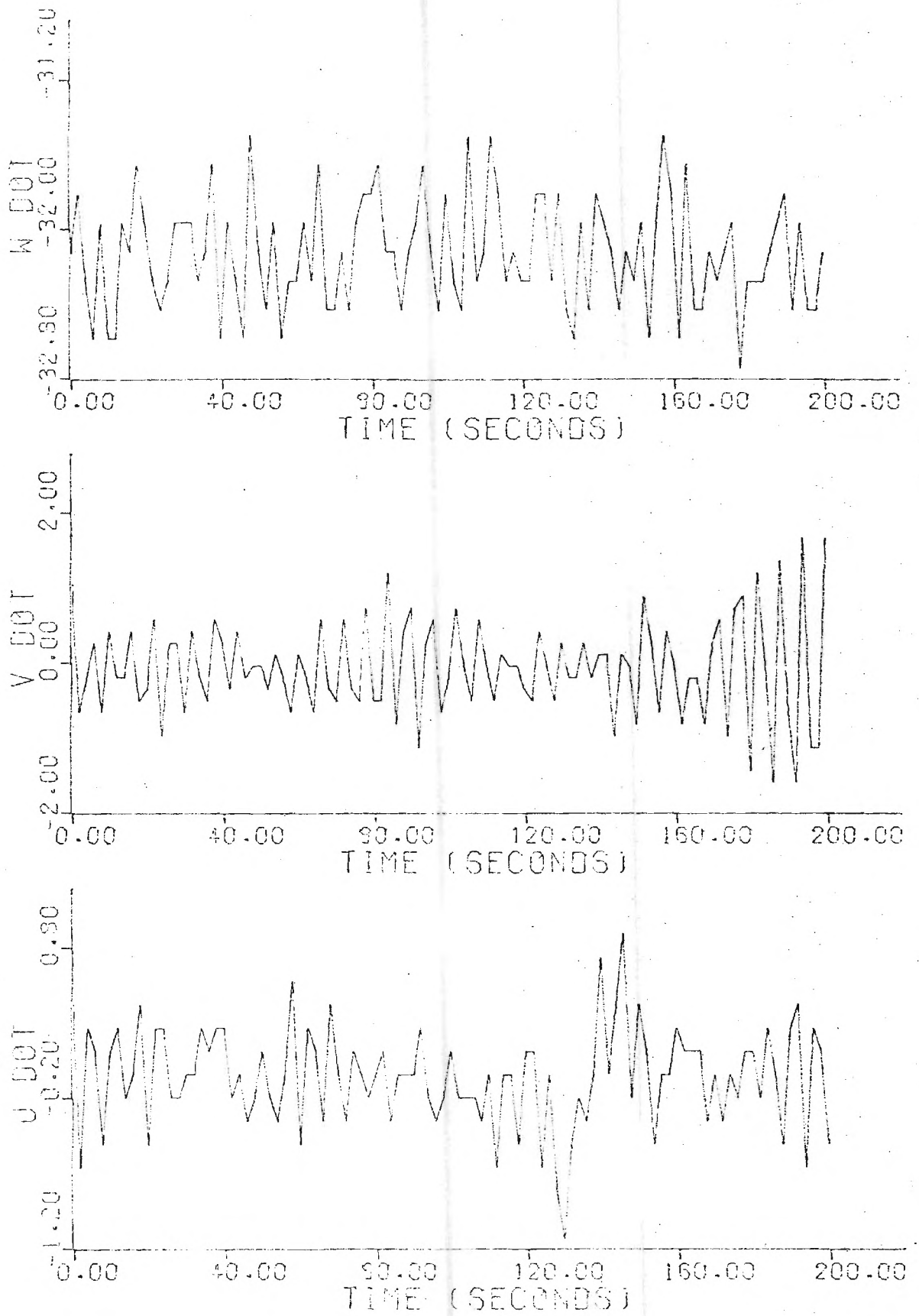


Figure 6.2 The Specific Forces in ft/sec.^{2} Obtained from File No. 5 of Tape No. 1479

6.2 Navigation

The data from the 5th file on tape No. 1479 were processed with the alignment and navigation algorithms implemented on our Univac computer. The first record in the file (40 samples) was skipped, and the second record was used for the alignment. The navigator began with the third record. The alignment routine estimated the initial roll and pitch angles at the end of the second record to be

$$\phi = 1.864443 \quad \text{degrees}$$

$$\theta = .051712047 \quad \text{degrees}$$

The outputs of the navigator--linear velocities, positions, and attitude--are plotted in Figures 6.3 through 6.5.

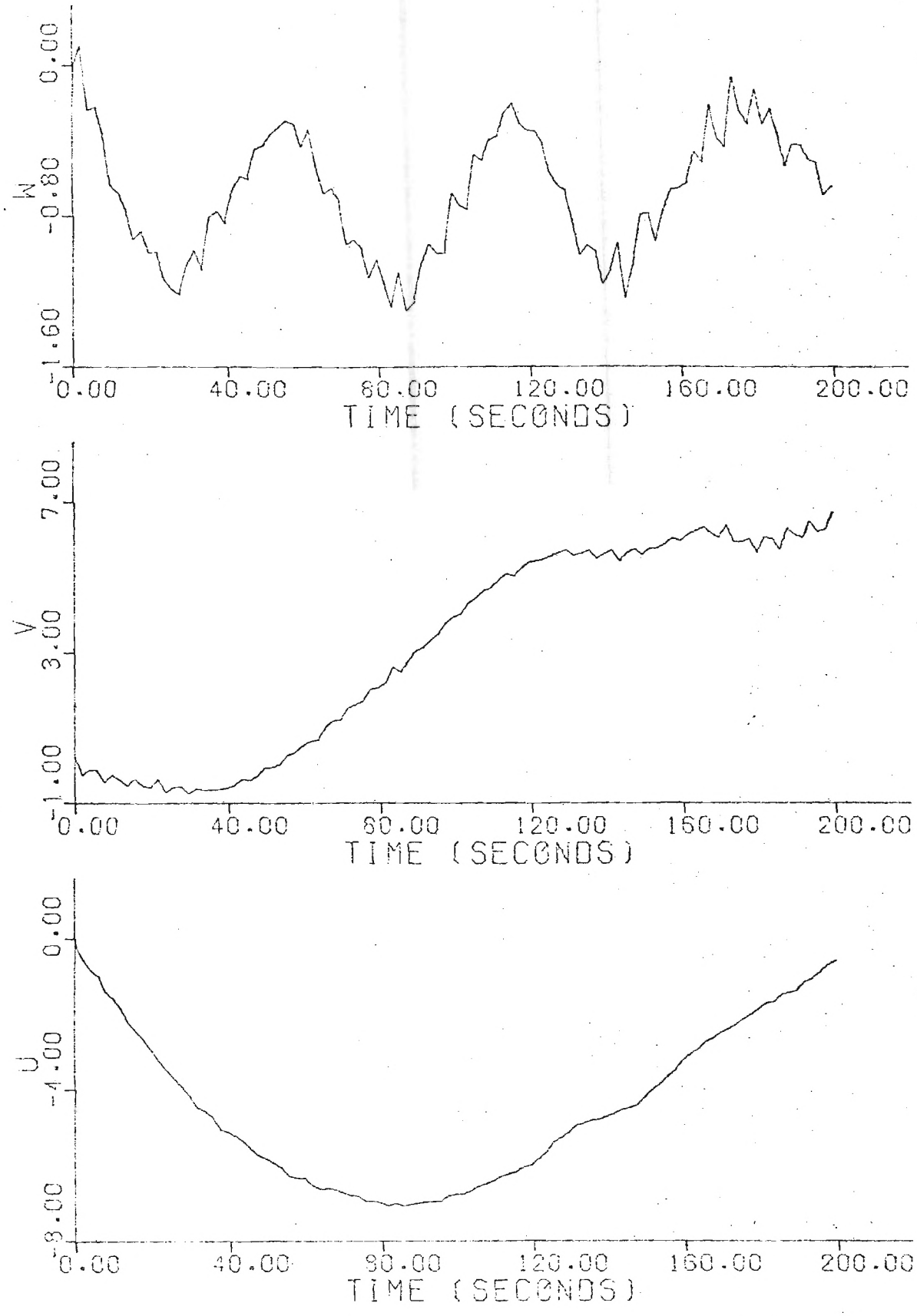


Figure 6.3 The linear velocities in feet/second for file no. 1479.

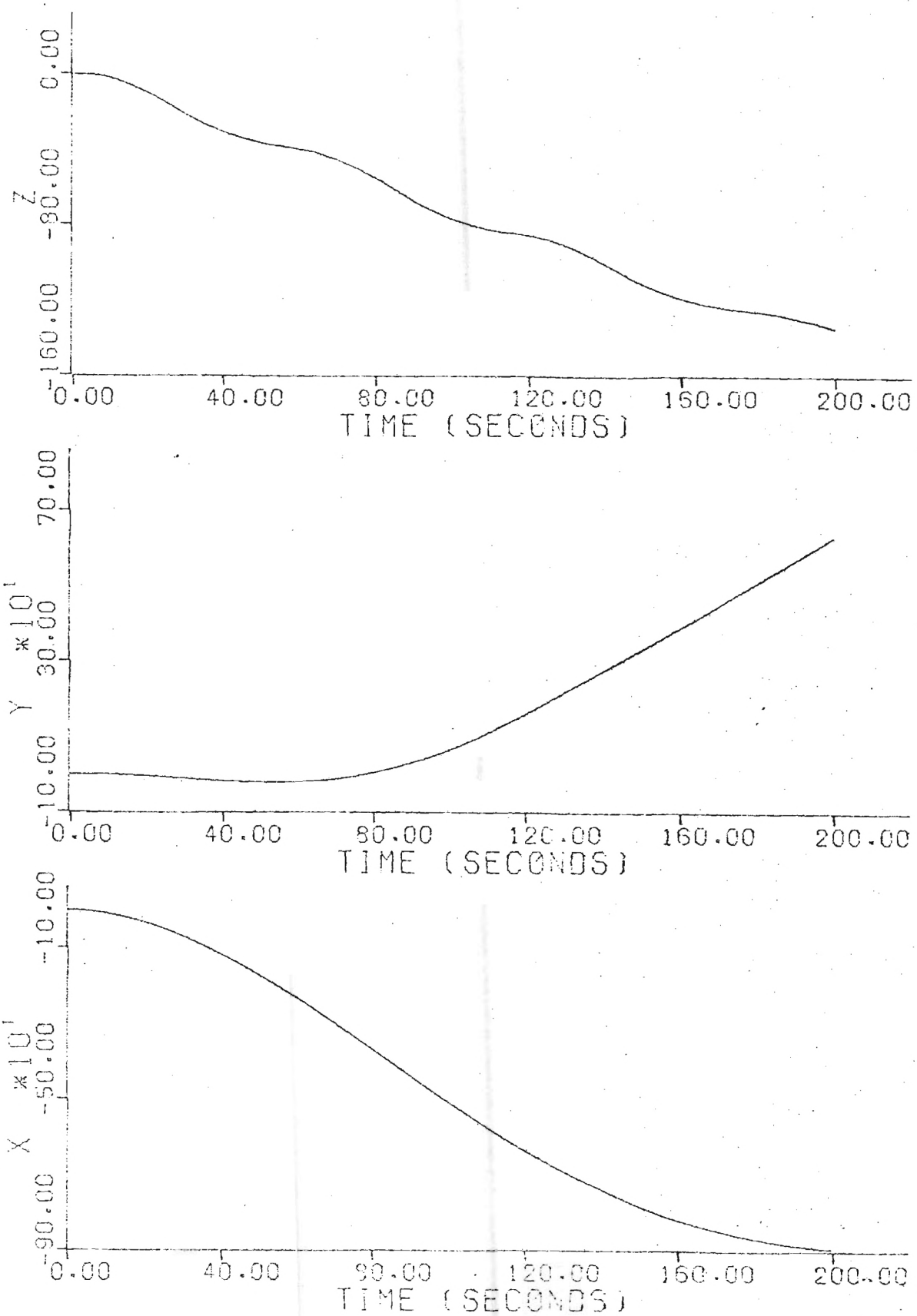


Figure 6.4 The position of the craft in feet for file no.5 of tape no. 1479.

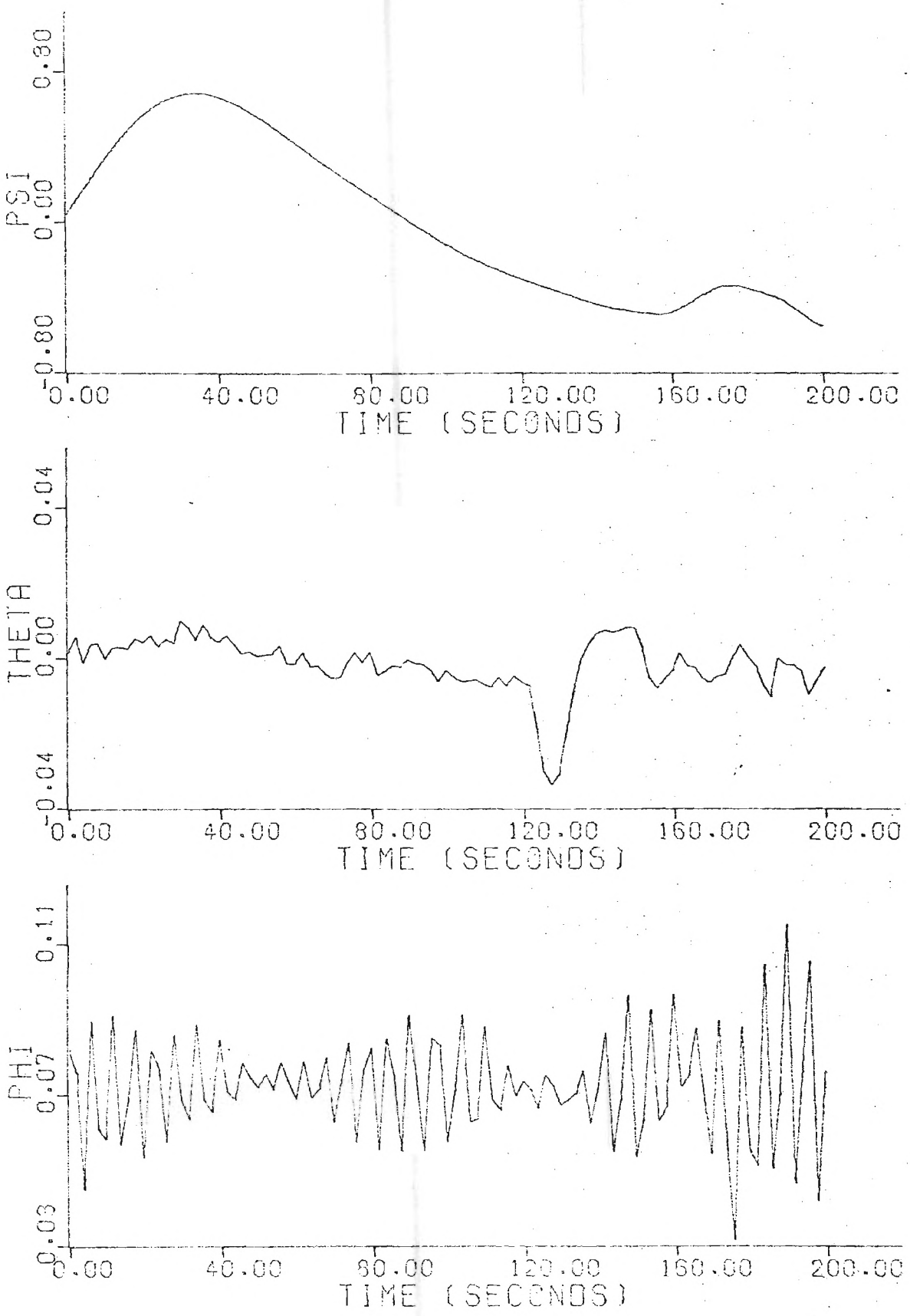


Figure 6.5 The attitude of the craft in radians for file no. 5 of tape 1479.

6.3 Identification Algorithms

The identification algorithm of Taylor, along with a test case, were implemented on our Univac computer. This was accomplished by duplicating the fortran program and data given in NASA-TN-D-6734. The cards were then copied on to datafiles and after extensive debugging, the algorithm converged to an answer for the test case given. At the suggestion of NCSL, a second test case has been set up which is similar to the systems we are trying to identify. It is a fourth order system with a lightly damped high frequency mode that is two decades above an almost critically damped mode. This problem is a good example of those that contain widely varying modes. The difficulty caused by this is best understood by considering the following. The period of the fast mode is one-hundredth of the period of the slow mode. If we want to observe the fast mode, we need at least ten points. At this sampling rate, we will need one thousand samples to observe one period of the slow mode. At present Taylor's program can handle a maximum of four hundred samples. The limitation on samples is caused by the procedure of storing the histories of the inputs and outputs in the active "core" of the computer. This situation can and will be easily remedied by storing the data in files during the execution of the programs. However, widely varying modes present a second problem that is not as easily circumvented. With widely different sizes of numbers it is probable that, at some point in the algorithm, large numbers will be subtracted to generate a small number--an ill-conditioning problem. When this occurs, the accuracy of the small number is questionable and the performance of the algorithms is impaired.

To eliminate this problem we propose to perform the identification in two stages. First, a fast sampling rate and a rather short time duration of data will be used to identify the fast mode. During this time the slow

mode will be considered constant--it doesn't have time to respond. Afterward, a slower sampling rate and a longer duration of time will be used to identify the slow mode. During this time, the fast mode identified in the first stage will be used. This approach requires the derivation of a procedure for transforming the system model into its Jordon canonical form. The required transformation matrix is a function of the unknown parameters! Therefore, some form of an iterative procedure must be derived.

Once the identification algorithm has been refined for our problem we will be able to run the identification process in the following mode.

1. Process the data using version 2 of the navigator.
2. Using the output of the navigator, identify the system.
3. With the system just identified process the data with both versions of the navigator, and combine their outputs via a Kalman filter.
4. Repeat steps 2 and 3 until the procedure converges.

7. Conclusions

The first step has been performed in developing an algorithm for extracting transfer functions from flight-test data. It is now proposed that the capabilities developed during the performance of this preliminary task be used to accomplish the stated objective--develop a computer system which processes flight-test data and produces accurate estimates of the vehicle's transfer functions.

Appendix A

The matrices used in (2.35)-(2.39) are defined as follows:

$$P_{LO} = \begin{bmatrix} m - X_{\dot{hu}} & -X_{\dot{hw}} & -X_{\dot{hq}} & 0 \\ -Z_{\dot{hu}} & m - Z_{\dot{hw}} & -Z_{\dot{hq}} & 0 \\ -M_{\dot{hu}} & -M_{\dot{hw}} & I_{yy} - M_{\dot{hq}} & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

$$A_{LO} = \begin{bmatrix} X_{hu} & X_{hw} & X_{hg} & X_{h\theta} + m(b-g) \\ Z_{hu} & Z_{hw} & mV_0 + Z_{hq} & Z_{h\theta} \\ M_{hu} & M_{hw} & M_{hq} & M_{h\theta} \\ 0 & 0 & 1 & 0 \end{bmatrix}$$

$$B_{LO} = \begin{bmatrix} X_{\delta_{FA}} & 0 & X_{h_{\delta_B}} & X_{h_{\delta_S}} \\ 0 & Z_v & Z_{h_{\delta_B}} & Z_{h_{\delta_S}} \\ M_{\delta_{FA}} & 0 & M_{h_{\delta_B}} & M_{h_{\delta_S}} \\ 0 & 0 & 0 & 0 \end{bmatrix}$$

P_{LAT} is a 5 x 5 matrix with the following components.

(1,1)	$m - Y_{\dot{hv}}$	(2,1)	$-(I_{zz}L_{\dot{hv}} + I_{xz}N_{\dot{hv}})/den$
(1,2)	$-Y_{\dot{hp}}$	(2,2)	$1 - (I_{zz}L_{\dot{hp}} + I_{xz}N_{\dot{hp}})/den$
(1,3)	$-Y_{\dot{hr}}$	(2,3)	$-(I_{zz}L_{\dot{hr}} + I_{xz}N_{\dot{hr}})/den$
(1,4),(1,5)	0	(2,4),(2,5)	0

(3,1) $-(I_{xz}L_{\dot{h}v} + I_{xx}N_{\dot{h}v})/den$

(3,2) $-(I_{xz}L_{\dot{h}p} + I_{xx}N_{\dot{h}p})/den$

(3,3) $1 - (I_{xz}L_{\dot{h}r} + I_{xx}N_{\dot{h}r})/den$

(3,4),(3,5) 0

(4,1),(4,2),(4,3),(4,5) 0

(5,1),(5,2),(5,3),(5,5) 0

(4,4),(5,5) 1

A_{LAT} is a 5x5 matrix with the following components

(1,1) Y_{hv} (2,1) $(I_{zz}L_{hv} + I_{xz}N_{hv})/den$

(1,2) Y_{hp} (2,2) $(I_{zz}L_{hp} + I_{xz}N_{hp})/den$

(1,3) $-mV_0 + Y_{hr}$ (2,3) $(I_{zz}L_{hr} + I_{xz}N_{hr})/den$

(1,4) $m(g-b) + Y_{h\phi}$ (2,4) $(I_{zz}L_{h\phi} + I_{xz}N_{h\phi})/den$

(1,5) $Y_{m\psi}$ (2,5) $(I_{zz}L_{h\psi} + I_{xz}N_{h\psi})/den$

(3,1) $(I_{xz}L_{hv} + I_{xx}N_{hv})/den$

(3,2) $(I_{xz}L_{hp} + I_{xx}N_{hp})/den$

(3,3) $(I_{xz}L_{hr} + I_{xx}N_{hr})/den$

(3,4) $(I_{xz}L_{h\phi} + I_{xx}N_{h\phi})/den$

(3,5) $(I_{xz}L_{h\phi} + I_{xz}N_{h\psi})/den$

(4,1),(4,3),(4,4),(4,5) 0

(5,1),(5,2),(5,4),(5,5) 0

B_{LAT} is a 5 x 4 matrix with the following components

(1,1) $Y_{\delta_{BP}}$

(1,2) $Y_{\delta_{SP}}$

(1,3) Y_{δ_B}

(1,4) Y_{δ_R}

(2,1) $(I_{zz}L_{\delta_{BP}} + I_{xz}N_{\delta_{BP}})/den$

(2,2) $(I_{zz}L_{\delta_{SP}} + I_{xz}N_{\delta_{SP}})/den$

(2,3) $(I_{zz}L_{h\delta_B} + I_{xz}N_{h\delta_B})/den$

(2,4) $(I_{zz}L_{h\delta_R} + I_{xz}N_{h\delta_R})/den$

(3,1) $(I_{xz}L_{\delta_{BP}} + I_{xx}N_{\delta_{BP}})/den$

(3,2) $(I_{xz}L_{\delta_{SP}} + I_{xx}N_{\delta_{SP}})/den$

(3,3) $(I_{xz}L_{h\delta_B} + I_{xx}N_{h\delta_B})/den$

(3,4) $(I_{xz}L_{h\delta_R} + I_{xx}N_{h\delta_R})/den$

MECHANICAL RESPIRATORS

by

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This report was prepared for the Naval Coastal Systems Laboratory by the School of Electrical Engineering at the Georgia Institute of Technology under Contract No. N61331-75-M-0610. The NCSL monitor for this contract was Mr. Beeman Ruthven.

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TABLE OF CONTENTS

1. INTRODUCTION

In any kind of an engineering development effort, small subsystems are built and assembled to form the resulting system. Questions always arise as to how subsystem specifications affect the performance of the overall system. Specifications that are too stringent cause the cost of the system to be more than necessary, while specifications that are not stringent enough cause a degradation in the performance of the system. Degradations in the performance of the system cannot be determined until the system is assembled, which results in costly delays. Too stringent specifications which raise the cost of the overall system may never be determined. In order to avoid these pitfalls, mathematical models for each of the subsystems should be developed, and the models connected together to form a mathematical model of the overall system. With such a model it is easy to vary the many parameters involved and investigate how various specifications affect the overall system performance. The charts and figures obtained would be invaluable to making design decisions.

At present, the Naval Coastal Systems Laboratory is in the process of securing for the U. S. Navy a portable volume controlled respirator capable of surviving combat conditions. It is hoped that we at Georgia Tech can apply our expertise in system analysis to developing mathematical models of the subsystems composing the respirator--the compressor, the accumulator, various valves, flowmeters, etc.--that can be used by us to aid the personnel at NCSL in making decisions affecting the cost and performance of the respirator.

In order to be able to contribute to this program we first surveyed the literature pertaining to the theory of ventilation and to existing

mechanical ventilators. The results of this study is Section 2 of this report in which we investigate and tabulate models of the various pieces of equipment comprising a ventilator. In Section 3, we apply these models to the GE-NAVY respirator and develop a crude model which is used to investigate how the dynamic response of the flowmeters affects the performance of the respirator.

Finally, in Section 4, we summarize the results of this effort and suggest future work.

2. MECHANICAL VENTILATION

The term ventilation means the movement of gases into and out of the lungs, while respiration, in addition to the movement of gases, includes the use of the oxygen in the gases--by enzyme systems producing energy, in the enrichment of the blood cells in the pulmonary artery, etc. Therefore, to be correct [1],[2], any mechanical device which merely aids a patient in pumping gases either in (inspiration), out (expiration), or both in and out of the lungs should be called a ventilator. However, engineers have never worried about being exact, we just want to be close enough; therefore, we will use the term in common use by anesthesiologists, respirator. No matter what they are called, mechanical respirators have now been in daily use by anesthesiologists for more than thirty years, and millions of patients with respiratory problems have been aided in breathing by them with very few cases of ill-effects [1]. However, because of the marked differences between mechanical ventialtion and the normal physiological mechanism of ventilation, certain precautions must be observed by the designers of respirators.

In the next section, we will investigate these differences.

2.1 Major Differences Between Natural and Mechanical Ventilation

Both mechanisms affect the movement of gases by differences in pressure. In normal breathing, inspiration results from an expansion of the thoracic cavity which causes a negative pressure within the thorax, the intrapleural pressure. The negative intrapleural pressure overcomes the elasticity of the lungs, causing them to expand and lower the pressure inside the alveoli to a point less than atmospheric pressure. The negative alveolar pressure

causes air to flow into the alveoli. Typical values for the differences in pressures involved are [1] a maximum of 2 cm H_2O between the exterior and the alveoli, and from 5 cm H_2O at the end of inspiration to 10 cm H_2O at the end of expiration between intrapleural and alveolar pressures. On the other hand, inspiration by a respirator is affected by applying gas at a pressure higher than atmospheric to the airway, which causes the gas to flow into the alveoli. As the gas fills the alveoli, the alveolar pressure, in marked contrast to the normal inspiration case, becomes greater than atmospheric, which causes the intrapleural pressure to become positive.

Although some respirators do aid the natural expiration by applying either a negative pressure or a pressure lower than alveolar pressure, most are passive during the expiratory phase, with the expiration of the alveoli being accomplished by the elasticity of the lungs and thorax forcing the gases out. Respirators which are passive during expiration are said to cause intermittent positive pressure ventilation (IPPV), those which apply negative pressure during expiration are said to cause positive-negative pressure ventilation, and those which apply a small positive pressure during expiration are said to cause continuous positive pressure ventilation [2].

The possible harmful effects of the use of respirators are primarily a result of the positive intrapleural pressure [1]. This interferes with the venous return to the heart and disturbs the distribution of blood and gases throughout the lungs. During normal inspiration, the negative pressure in the thorax also sucks blood from outside the thorax into the great thoraic veins and into the heart. The positive pressure associated with respirators causes substantial changes in this process. In normal breathing the minimum intrapleural pressure during inspiration is much less than the minimum intrapleural pressure during expiration, which causes the venous return to be the greatest during inspiration. With mechanical ventilation, the

intrapleural pressure is smallest during expiration, causing the venous return to be greatest during expiration. The positive pressure in the lungs causes them to compress the heart as they expand. The greater the peak pressure and the longer it lasts, the more it will affect the cardiac output. Normal pulmonary capillary blood pressure is $\approx$ 12 cm H_2O; therefore, when alveolar pressure becomes positive, these capillaries are compressed which makes it more difficult for the right ventricle to pump blood through them. These factors are important with patients who have an intact thorax.

An obvious possibility of positive pressure in the lungs is the rupture of the lungs themselves. The minimum pressure required to rupture an exposed and unsupported lung is between 40 to 80 cm H_2O [1]. When the lung is supported by the thoraic cage and musculature, a pressure of 80 to 140 cm H_2O is required. Therefore, the maximum safe alveolar pressure is $\approx$ 70 cm H_2O for a patient with an intact thorax [1] and $\approx$ 30 cm H_2O for a patient undergoing thoraic surgery.

A more difficult problem to deal with is the uneven distribution of gases in the lung. Perfusion with venous blood of insufficiently ventilated sections of the lung will result in blood that is insufficiently oxygenated being returned to the left ventricle of the heart--a shunt from the right ventricle to the left. On the other hand, ventilation of insufficiently perfused regions of the lung results in some of the oxygen not being used to oxygenate the blood, which causes an increase in the PCO_2 of the blood. There is evidence which indicates that during normal breathing various regions of the lung are used and rested interchangeably, while with mechanical ventilation, the gas flows in the same way every cycle resulting in the same distribution [2].

The metabolic problems are overventilation and underventilation, each term referring to deviations from normal ventilation. Of the two, the first

is the more desirable and is used during surgery. It guarantees good oxygenation and carbon-dioxide elimination. The PO_2 of the blood goes up while the PCO_2 goes down. However, the change from the normal conditions does produce changes in tissue activities; therefore, long periods of overventilation should be avoided. There seems to be no possible good from underventilation. The PCO_2 of the blood goes up while the PO_2 goes down, which can lead to a coma and damage to individual organs [1].

Finally, when a mask is used, it is possible to inflate and rupture the patient's stomach. In this situation, it is suggested that the pressure at the patient's mouth be limited to 15 cm H_2O.

In Section 2.3 design techniques will be suggested for alleviating these problems.

2.2 Different Types of Respirators

In order to classify and analyze the different types of respirators, we will now present mathematical models of a respirator and lung. Using these models one can classify most of the respirators in common use into either flow generators or pressure generators [1].

2.2.1 Compliance

Although the mathematical relationship between the pressure and volume of the gas in an elastic container is nonlinear

$$V = f(p) \tag{2.1}$$

where V is the volume and p is the pressure, as long as we are interested in only small changes in pressure and volume from some operating point, we can describe the changes with a linear model. First (2.1) is expanded in a Taylor's series about the operating point (V_0, P_0)

$$V = f(P_0) + \left.\frac{\partial f}{\partial P}\right|_{P=P_0} (P - P_0) + \frac{1}{2} \left.\frac{\partial^2 f}{\partial P}\right|_{P=P_0} (P - P_0)^2 + \text{HOT.} \tag{2.2}$$

where HOT are the higher order terms in the expansion [terms involving $(p-p_0)^3$, $(p-p_0)^4$, etc.]. Next we restrict our range of interests to values of pressure for which $(p-p_0)^2$ is much smaller than $(p-p_0)$, then (2.2) yields the linear model.

$$v = Cp \tag{2.3}$$

where the deviation volume and pressure are $v = V - f(P_0)$ and $p = p-p_0$, and the compliance of the container is $C = \frac{\partial f}{\partial P_0}$. The operating point for the lungs and chest wall is the volume and pressure of the lung at rest--P_0 = atmospheric pressure and $f(p_0) \approx 1$ liter [2]. The compliance of the lungs alone of an average man, awake and erect, is $\approx .2$ liter/cm H_2O [1],[2]. When anesthetized the compliance of the lungs alone of the average man is ≈ 1 liter/cm H_2O [1]. The total compliance is a combination of the compliance of the lungs and that of the chest wall. For a supine, anesthetized, relaxed patient, the total compliance varies from .02 to .14 liter/cm H_2O, while for conscious patients, the total compliance is $\approx .1$ liter/cm H_2O [1].

2.2.2 Resistance

The two basic physical laws that govern the flow of fluid through passageways are [2]:

Hagen-Poiseuille Law

During laminar flow the velocity of a volume of fluid flow through a straight tube of uniform bore is directly proportional to the pressure exerted to move the fluid, and directly proportional to the fourth power of the diameter.

And in passageways which are irregular and cause turbulent gas flow, the following applies.

Darcy-Weisbach Law

Turbulent gas flow rate is proportional to the square root of the pressure exerted to move the gas.

The gas flow rate is also a function of the density and the viscosity of the gases used. For instance, for turbulent flow, substituting helium for nitrogen in air yields a gas which requires one-third the pressure increase to double flow rates.

For a particular gas and passageway, and laminar flow, we have

$$p_{in} - p_{out} = R\,\dot{v} \tag{2.4}$$

where p_{in} and p_{out} and $\dot{v}$ are the deviation pressures at the input and output of the passageway and gas flow-rates and R is the resistance of the passageway. Unfortunately, the normal airway is not of uniform diameter--it is quite irregular--and turbulent flow through them is the rule rather than the exception [2]. However, one can make the following observation. At low flow rates, the flow will certainly be laminar and (2.4) will be valid. Turbulent flow will not begin until the flow rate has built up. At that time we must use

$$p_{in} - p_{out} = K\,\dot{v}^2 \tag{2.5}$$

where K is a proportionality constant. But, since $\dot{v} \neq 0$, we can expand the right side of (2.5) in a Taylor's series and obtain linear terms.

$$P_{in} - P_{out} = K\,\dot{V}_1^2 + 2K\dot{V}_1\,(\dot{V} - \dot{V}_1) + K(\dot{V} - \dot{V}_1)^2 + \text{HOT} \tag{2.6}$$

If we assume $(\dot{V} - \dot{V}_1)^2 \ll \dot{V}_1(\dot{V} - \dot{V}_1)$, then (2.6) yields

$$P_{in} - P_{out} = R'\,\dot{v} \tag{2.7}$$

where $R' = 2K\dot{V}_1$. It is proposed that the relationship between $\dot{v}$ and $(p_{in} - p_{out})$ shown in Figure 2.1 be used.

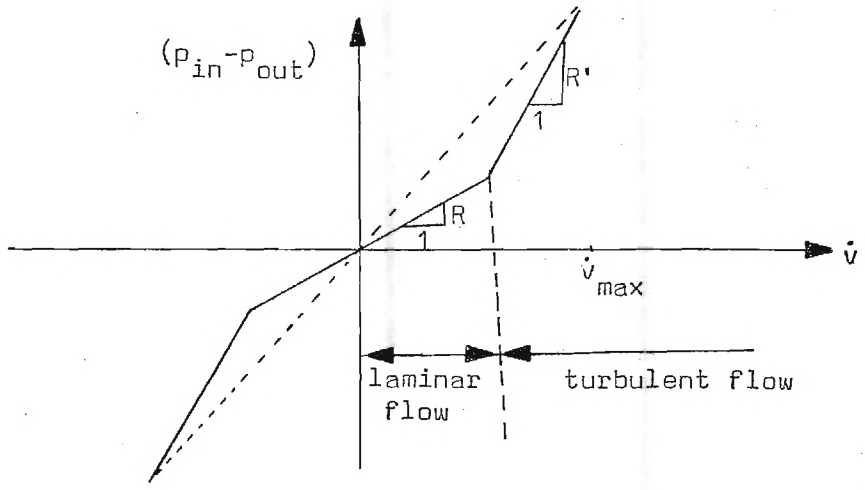


Figure 2.1 Quazi-Linearized Flow-Rate, Pressure Relationship

If $\dot{v}$ is less than $\dot{v}_{max}$ it is proposed that the dotted line in Figure 2.1 be used as the flow-rate, pressure relationship. That is,

$$(p_{in} - p_{out}) = R'' \dot{v} \tag{2.8}$$

2.2.3 Patient Model

We are now in a position to use the first-order RC lung model, postulated by Campbell and Brown [3], shown in Figure 2.2.

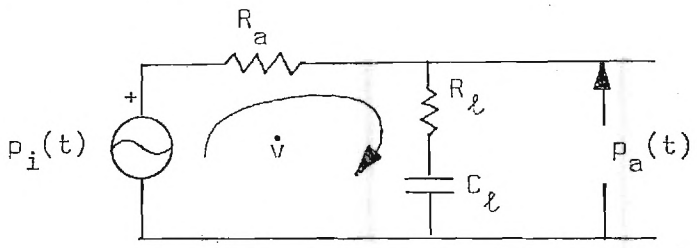


Figure 2.2 Brown and Campbell's Lung Analog

In Figure 2.2, p_i is the applied pressure, R_a is the airway resistance, R_ℓ is the resistance of the lung tissue and chestwall, C_ℓ is the compliance

of the lung and chestwall, p_a is the alveolar pressure, and v is the deviation volume.

2.2.4 System Models

2.2.4.1 Inspiratory Phase

First we will consider the case of a constant pressure source p_s with a resistance R_s from the point where the pressure is generated to the mouth. The model during the inspiratory phase becomes

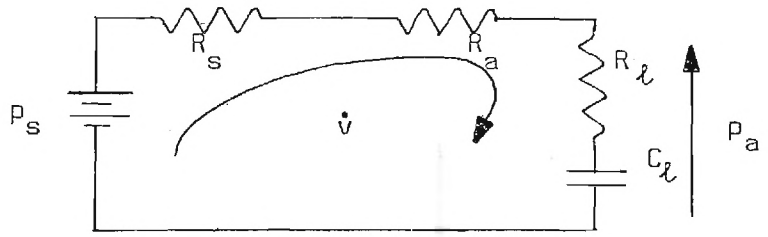


Figure 2.3 The Constant Pressure Model

By using circuit analysis techniques [4], one obtains the two nodal equations for the model of Figure 2.3.

$$\dot{v} = \frac{p_s - p_a}{R_s + R_a} \tag{2.9}$$

$$\dot{v} = \frac{p_a - v/c_\ell}{R_L} \tag{2.10}$$

Eliminating p_a via (2.9) and (2.10) yields

$$\dot{v} = p_s/R_T - v/\tau \tag{2.11}$$

where $R_T = R_s + R_a + R_L$ and $\tau = R_T C_\ell$. The solution to (2.11) is

$$v(t) = (1 - e^{-t/\tau}) C_\ell p_s \tag{2.12}$$

Observe that (2.12) yields the change in the volume of gases in the lung as a constant pressure source is applied. A plot of the deviation volume in the alveoli versus time is given in Figure 2.4.

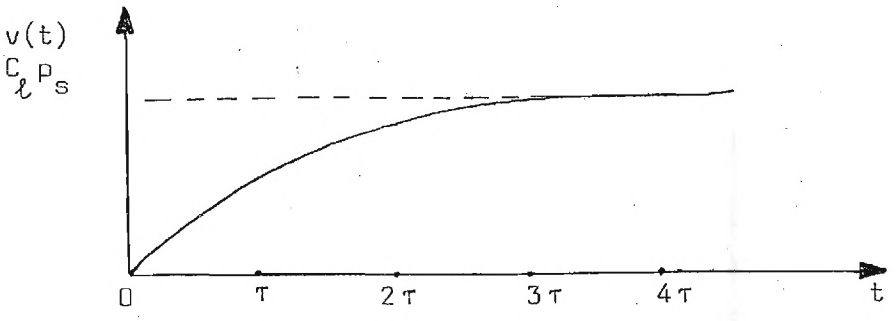


Figure 2.4 A Plot of the Deviation Volume of Gas in the Alveoli Versus Time when a Constant Pressure p_s is applied

Differentiating (2.12) yields an expression for the gas flow rate.

$$\dot{v}(t) = \frac{R_s}{R_T} e^{-t/\tau} \tag{2.13}$$

which is plotted in Figure 2.5.

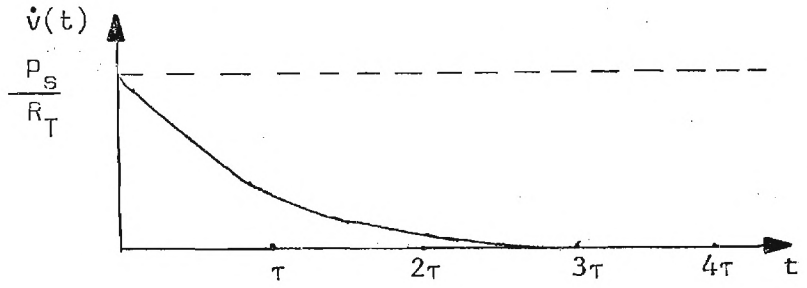


Figure 2.5 A Plot of the Gas Flow Rate Versus Time when a Constant Pressure p_s is applied

Another quantity of concern is the deviation pressure in the alveoli. From Figure 2.3 we observe that p_a is given by

$$p_a(t) = \dot{v}(t)R_\ell + v(t)C_\ell$$

or

$$p_a(t) = p_s\left(\frac{R_\ell}{R_T}\right) e^{-t/\tau} + p_s(1 - e^{-t/\tau}) \tag{2.14}$$

The first term on the right side of (2.14) results from the resistance of the lung tissue and chestwall to gas flow while the second term results from the elasticity of the lungs and chestwall. A plot of the resistance term would be Figure 2.5, with (p_s/R_T) replaced by $(p_s R_\ell/R_T)$, while a plot of the elasticity term would be Figure 2.4 with $(c_\ell p_s)$ replaced by (p_s).

Finally, an examination of Figure 2.3 shows that the pressure at the patient's mouth is given by

$$p_m(t) = p_s - \dot{v}(t)R_s$$

or (2.15)

$$p_m(t) = p_s\left(1 - \frac{R_s}{R_T} e^{-t/\tau}\right)$$

A plot of the pressure at the mouth versus time is given in Figure 2.6.

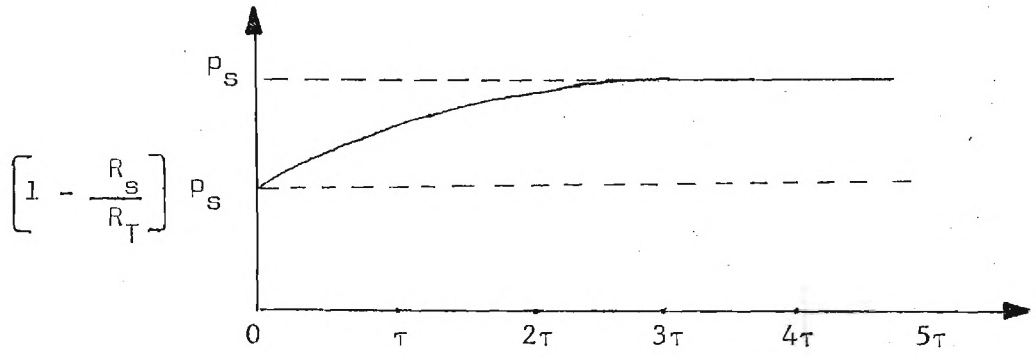


Figure 2.6 A Plot of the Pressure at the Mouth Versus Time when a Constant Pressure p_s is applied

In order to get a feel for the times, volumes, and pressure involved we use the following values for the parameters:

$c_\ell = 0.1$ liter/cm H_2O

$R_a = 1.5$ cm H_2O/liter/sec.

$R_s = 2$ cm H_2O/liter/sec.

$R_\ell = 1.2$ cm H_2O/liter/sec.

$p_s = 12$ cm H_2O

For these values, we have

1) Total Resistance $R_T = R_s + R_a + R_\ell = 4.7$ cm H_2O(liter/sec.)

2) Time Constant $\tau = R_T C_\ell = .47$ seconds

3) Volume of gas delivered to lungs $C_\ell p_s = 1.2$ liters

4) Maximum Flow Rate $(p_s/R_T) = 2.6$ liters/sec.

5) Minimum pressure at the mouth $1 - \left(\frac{R_s}{R_T}\right) p_s = 6.9$ cm H_2O

Observe in Figures 2.4 through 2.6 that the transients are over in ≈ 3 time constants, which is 1.41 seconds. Therefore, for these parameters and a constant pressure source, the inspiration phase is over in 1.41 seconds.

We can get the constant flow source model easily from the constant pressure source model. We will simply make use of the Taylor's series for exponentials

$$e^{-t/\tau} = 1 - t/\tau + \frac{t^2}{2!\tau^2} + \frac{t^3}{3!\tau^3} + \ldots \tag{2.16}$$

by observing that, for times much less than the time constant , the exponential can be accurately approximated by

$$e^{-t/\tau} = 1 - t/\tau \tag{2.17}$$

The largest error in using (2.17) for (2.16) is proportional to $(t/\tau)^2$, which will be small as long as we limit the inspiratory phase to times much less than the time constant. Substituting (2.17) into (2.12) through (2.15) yields:

$$v(t) = C_\ell p_s (t/\tau) \tag{2.18}$$

$$\dot{v}(t) = \frac{p_s}{R_T} (1 - t/\tau) \tag{2.19}$$

$$p_a(t) = p_s\left(\frac{R_\ell}{R_T}\right) + p_s\left(1 - \frac{R_\ell}{R_T}\right) (t/\tau) \tag{2.20}$$

$$p_m(t) = p_s\left[1 - \frac{R_s}{R_T}(1 - t/\tau)\right] \tag{2.21}$$

Next, we observe that the time constant is made small by increasing R_s ($\tau = (R_s + R_a + R_\ell)C$); therefore, $R_s/R_T \to 1$ and for large resistances t/τ becomes much less than 1 which yields the constant flow equations

$$v(t) = \dot{v}\, t \tag{2.22}$$

$$\dot{v}(t) = p_s/R_s \tag{2.23}$$

$$p_a(t) = p_s(R_\ell/R_T) + (p_s/R_s C_\ell)t \tag{2.24}$$

$$p_m(t) = (p_s/\tau)t \tag{2.25}$$

Observe that in order for the volume in the lungs to build up rapidly the flow rate $\dot{v}$ must be high, or, the pressure of the supply, p_s, must be high. Therefore, constant flow-rate is obtained with a high constant pressure, high resistance source.

These are the two basic respirators, and their merits will be discussed in the section on parameter sensitivities.

A slightly more complicated source is made up of a constant volume source with a reservoir bag as shown in Figure 2.7.

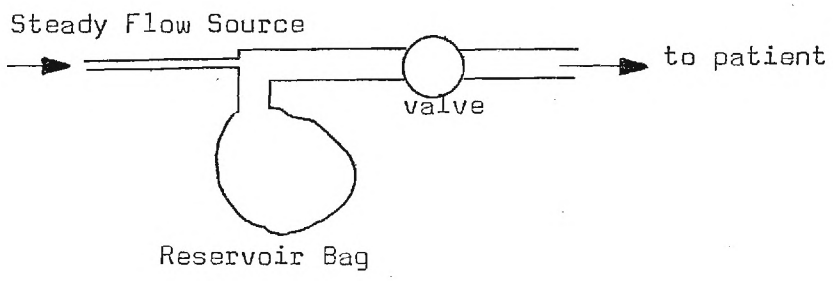


Figure 2.7 A Steady Flow Source with a Reservoir Bag

The electrical analogue for this generator configuration is a constant current source in parallel with a capacitor and with a resistor representing the valve and tubing between the bag and patient. This is shown in Figure 2.8.

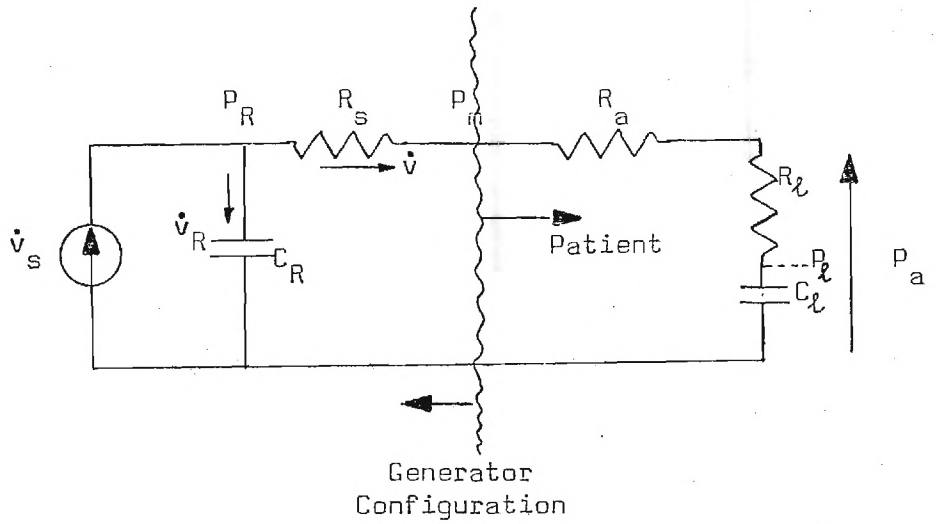


Figure 2.8 The Electrical Analogue of the Steady Flow Source with a Reservoir

Using circuit analysis techniques, we find that the differential equations describing the source-lung model of Figure 2.8 are

$$\begin{bmatrix} \dot{v}_R \\ \dot{v}_\ell \end{bmatrix} = \begin{bmatrix} -1/R_T C_R & 1/R_T C_L \\ 1/R_T C_R & -1/R_T C_L \end{bmatrix} \begin{bmatrix} v_R \\ v_\ell \end{bmatrix} + \begin{bmatrix} 1 \\ 0 \end{bmatrix} \dot{v}_s \qquad (2.26)$$

whole solutions are

$$\begin{bmatrix} v_R(t) \\ v_\ell(t) \end{bmatrix} = \begin{bmatrix} \frac{C_T}{C_L}(1-e^{-t/\tau}) + e^{-t/\tau} & \frac{C_T}{C_L}(1-e^{-t/\tau}) \\ \frac{C_T}{C_R}(1-e^{-t/\tau}) & \frac{C_T}{C_R}(1-e^{-t/\tau}) + e^{-t/\tau} \end{bmatrix} \begin{bmatrix} v_R(0) \\ v_\ell(0) \end{bmatrix}$$

$$+ \begin{bmatrix} \frac{C_T}{C_L}\left[t - \tau(1-e^{-t/\tau})\right] + \tau(1-e^{-t/\tau}) \\ \frac{C_T}{C_R}\left[t - \tau(1-e^{-t/\tau})\right] \end{bmatrix} \dot{v}_s \qquad (2.27)$$

where $C_T = C_L C_R/(C_L + C_R)$, $R_T = R_a + R_s + R_\ell$, and $\tau = R_T C_T$. The equations in (2.27) are more complicated than the ones we had before; however, the responses are basically the same--exponential with a ramp added.

In many situations gas at a very high pressure is applied through an orifice, which can be thought of as a high resistance, to be diffused with a second gas. We will model this process as simply a high pressure source in series with a large resistance

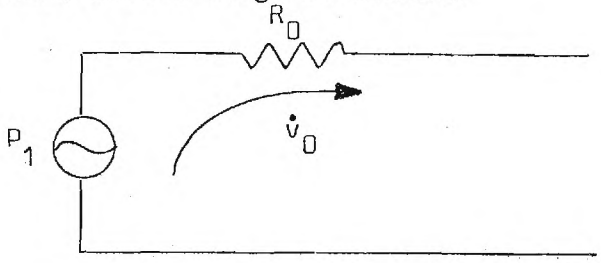


Figure 2.9 A Model of a High Pressure Source Supplying Gas through an Orifice

Leaks can be inserted intentionally to control the flow rate or can occur because of an accident, because of wear and tear on the machinery, etc. In any case, we can analyze their effects by inserting a resistor between the point they occur and the atmosphere, as is shown in Figure 2.10.

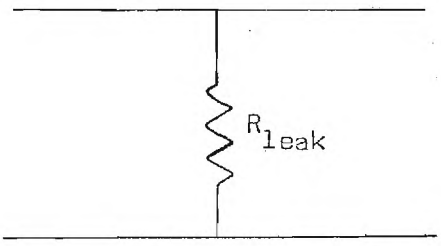


Figure 2.10 The Model that will be used for Leaks

2.2.4.2 Switch Over from Inspiration to Expiration

There are several techniques for switching from one mode to the other. The decision to switch can be based on elapsed time, pressure at the mouth, volume of gas supplied, gas flow rate, etc. We will in a later section be analyzing respirators whose switching logics are based on pressure and volume. In particular, we will investigate the effects of time lags and

errors inherent to the measuring devices. For the volume method of switching we will use the following model and assume that the integrator

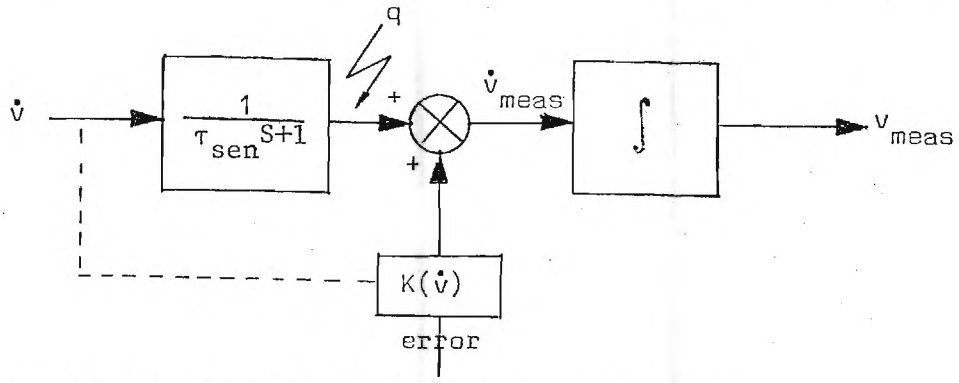


Figure 2.11 A Model of the Volume Sensing Device

in the second block is reset to zero at the beginning of each inspiration. In Figure 2.11, we have included an error source that represents the error in the output of the flow sensor after it reaches steady-state, the lag effects have died out. We are allowing that error to be a function of the flow rate being measured. The differential equations describing the proposed model are

$$\dot{q} = -\frac{1}{\tau_{sen}} q + \frac{1}{\tau_{sen}} \dot{v} \tag{2.28}$$

$$\dot{v}_{meas} = q + K(\dot{v})\, e \tag{2.29}$$

2.2.4.3 Expiratory Phase and the Switch over from Expiration to Inspiration

The expiratory phase of the respiration is usually affected by the elasticity of the lungs. The pressure at the source ranges from a few cm H_2O negative to a few cm H_2O positive [1]. The respirator designs available range from constant pressure-low resistance to high pressure-high resistance (constant flow-rate) sources. The models and equations for the expiration phase are almost identical to those of the inspiration phase and will not be repeated here.

As with the switch over from inspiration to expiration, there are four basic techniques for detecting the time for switching from expiration to inspiration--elapsed time, pressure at the mouth, volume of gas removed and gas flow-rate. In addition, in the control-assist mode, the switchover is initiated when the patient attempts to begin inspiration (a small negative pressure is detected or a pressure more negative than the negative pressure of the source is detected).

2.3 Suggestions For Respirator Design

In order to minimize the cardiovascular effects of mechanical ventilation, one should attempt to reduce the average value of the alveolar pressure, where the average is taken over one cycle [1].

$$p_{ave} \triangleq \frac{1}{T} \int_0^T p(t)dt$$

Observe that in using the average value of the alveolar pressure as a measure, we are considering both the amplitude and the duration of the pressure--a high pressure for a short duration is no worse than a lower pressure for a longer period of time. The techniques suggested in [1] and [2] for minimizing the mean alveolar pressure are:

1) Positive pressure should be used only to affect the desired volume exchange.
2) Inspiration time should be less than expiration time ($I/E < 1$).
3) The lungs should be inflated with rapid flows of gas.
4) Expiratory resistance should be low.
5) The dead space should be small.
6) Small negative pressures may be applied during the expiratory phase.

Some of these recommendations are rather confusing and require a closer look. The objective of number one is to allow the intrapleural pressure to decrease to normal as quickly as possible; on the other hand, there is reason to believe that keeping the pressure in the alveoli constant for a short period of time after the alveoli is inflated allows for a more even ventilation of the gases. However, it is shown in [1] that the additional time of positive pressure has serious effects on the central venous and arterial pressures.

There seems to be pretty complete agreement on recommendation number two, both in [1] and [2] and in the additional references referred to at the end of this report. Again, the purpose is to remove the positive pressure from the cardiovascular system as much as possible. The third recommendation has the same objective; however, high flow rates are questionable for other reasons. At flow rates above the critical velocity of the gases, the flow becomes turbulent in regions where it would normally be laminar and the pressure required to move the gas becomes proportional to the square of the flow-rate, which increases the airway pressure. This leads to uneven distribution of the gases and increases the dead space. In certain disease states, which make the airways more susceptible to this condition, and with children and infants (because of small diameters of airways--high resistance), low flow-rates, which produce laminar flow are desirable [2].

Recommendations four and five seem to be obvious; however, number six is not. The purpose is to have a slight negative pressure in the lungs at the beginning of inspiration. By slight we mean something less than 15 cm H_2O as opposed to a suction catheter whose pressure exceeds 500 cm H_2O. However, the detrimental effects of negative pressure during expiration seem to be numerous. It has been reported to have induced ventricular arrhythmia in

anesthetized patients during hypothermia [2]. It also leads to airway narrowing, air trapping and to an increase in dead space [2].

2.4 Testing and Specifications for Respirators

After discussion with various physicians, we were referred to Dr. L. Rendall-Baker, who then asked Dr. Meyer Sakland to forward to us a copy of the "Proposed ANSI Standard Specifications for Breathing Machines for Medical Use, Z-79.7." A copy of this document is included as Appendix A of this report. Although the ANSI document does not attempt to specify the ideal machine (no one knows what it is!), it does specify the parameters that the manufacturer should supply, the minimum acceptable accuracies of various valves and controls, the various electrical specifications, etc., and it also specifies how to test a respirator. Also, included as Appendix B is a document prepared by Mr. Ken Watkinson of NCSL that contains electrical specifications for medical devices.

3. THE GE-NAVY PORTABLE VOLUME CONTROLLED RESPIRATORS (PVCR)

As with any engineering development effort, questions have arisen as to the effect specifications pertaining to specific pieces of hardware will have on the overall performance of the respirator. As would be expected, there are tradeoffs to be made between the cost of equipment and meeting those specifications. The actual performance of the overall respirator system cannot be determined until the individual pieces of hardware--flowmeter compressor, accumulator, valves, etc.--have been built and assembled. At that time, it is rather expensive to find out that one of the pieces of component hardware has to be either replaced or redesigned in order for the respirator system to perform adequately. Another problem, just as serious in these days of belt-tightening, is to discover that the extracting specifications placed on a piece of hardware could have been eased without degradating the performance of the respirator, which would have allowed the use of much more inexpensive pieces of hardware.

Although the exact effects of the various components on the respirator performance cannot be determined until the respirator is assembled, by developing mathematical models that describe the respirator, we can predict those effects while the hardware is being developed. In fact short of inserting representative samples of all possible variations of that piece of hardware into the respirator, the only way to determine how a particular piece of hardware affects the respirator performance is via mathematical models.

Two mathematical models of the respirator are needed, one overly simplified to allow "back of the envelope" type calculations and the other more detailed to verify those calculations. The simplified model, which

would be based on laminar flow and the use of average resistances and compliances, would be used to obtain a better understanding as to how various design parameters affect the overall respirator performance. The detailed model would include nonlinearities such as turbulent flow, valves not opening until a certain pressure difference is developed, etc., and would be used to verify the conclusion drawn from the simplified model. The detailed model, because of its complexity must be programmed on a digital computer.

As a first step, a simplified model for a particular phase of the GE-NAVY PVCR will be developed, and it will be used to address some of the questions raised in [5].

3.1 The Simplified Model

A schematic, obtained from [6], of the GE-NAVY respirator is shown in Figure 3.1. As a first step we will develop a simplified model for the open-cycle, controlled breathing mode. A block diagram of the components of the respirator in this configuration is given in Figure 3.2. The model is obtained by replacing each block in the diagram with its electrical analogue (see Section 2). The numbers used in the analogues are from [6]. The compressor is modelled as a constant flow generator supplying 0.5 liter/sec. The accumulator is modelled as a compliance in parallel with the flow generator. The compliance used is calculated from the fact that "the accumulator is sized to store 2.5 liters of air at 90 cm H_2O" [6]. This yields a compliance of .028 liters/cm H_2O. The inhale and exhale flow valves are each modelled as an on-off switch and a resistance. At the present time, we do not have a good value for the resistance; however, as the exact value is not critical in our initial analysis, we will arbitrarily assign it a value of 1 cm H_2O(liter/sec). The bypass valve on the diaphragm

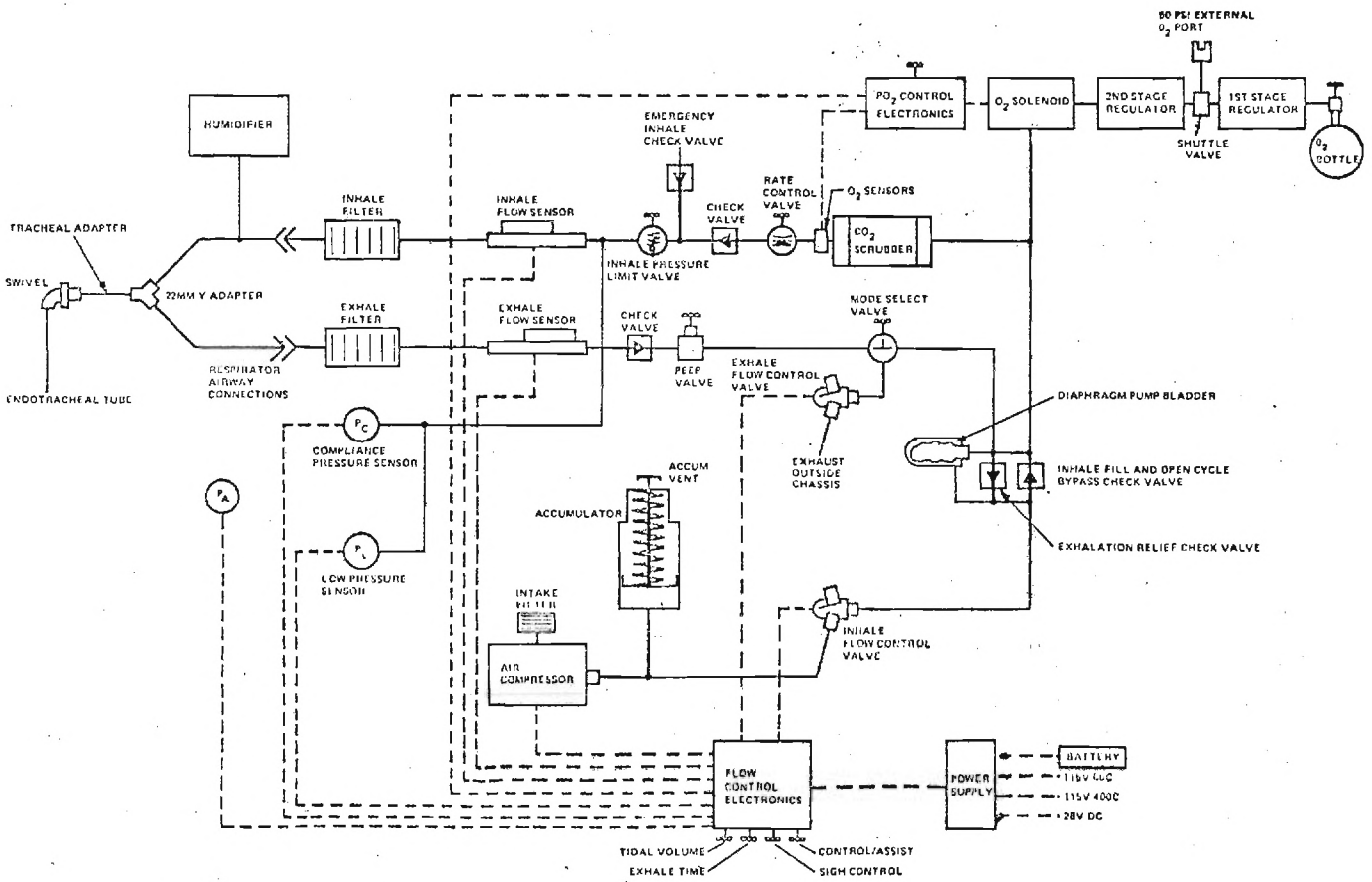


Figure 3.1 A Schematic of the GE-NAVY Respirator

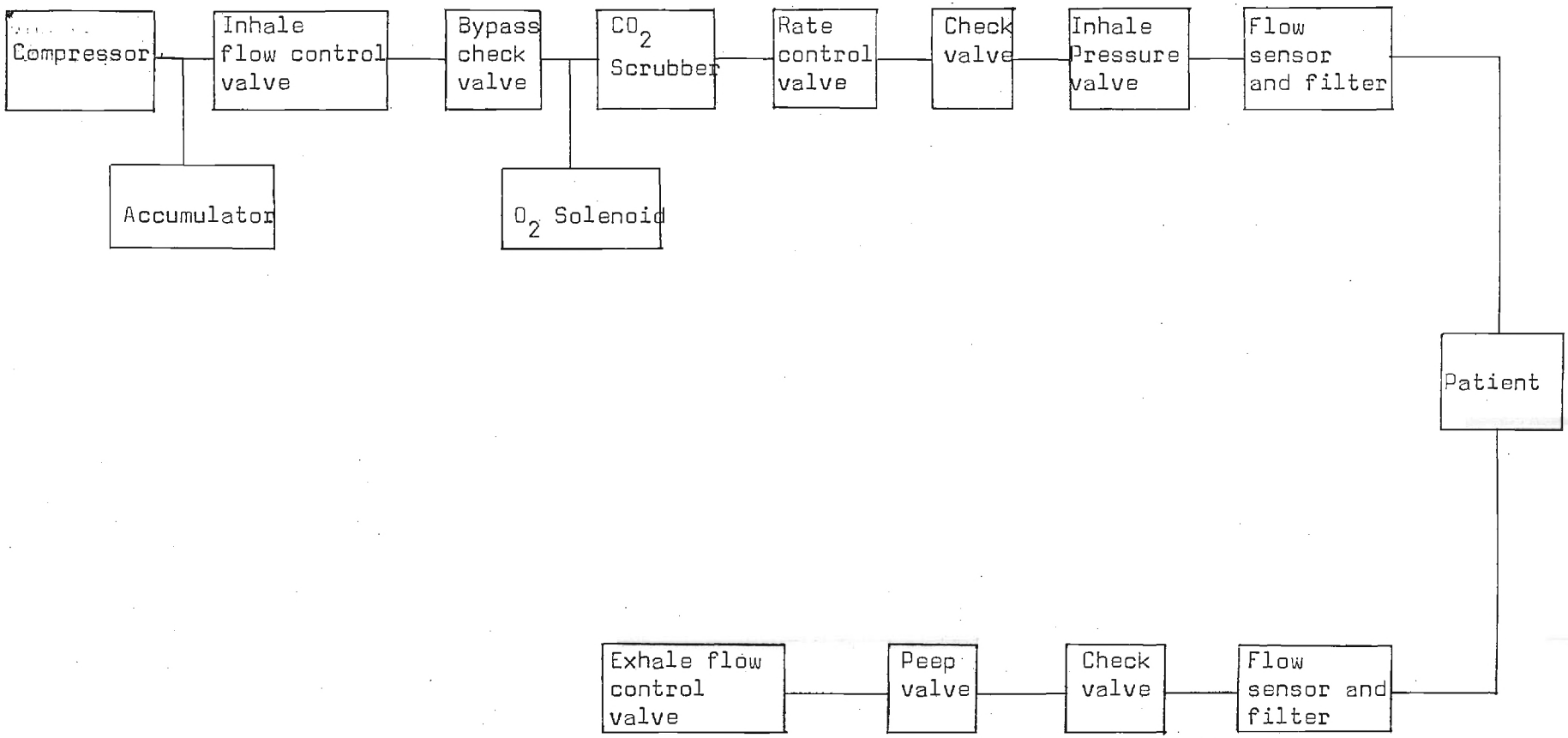
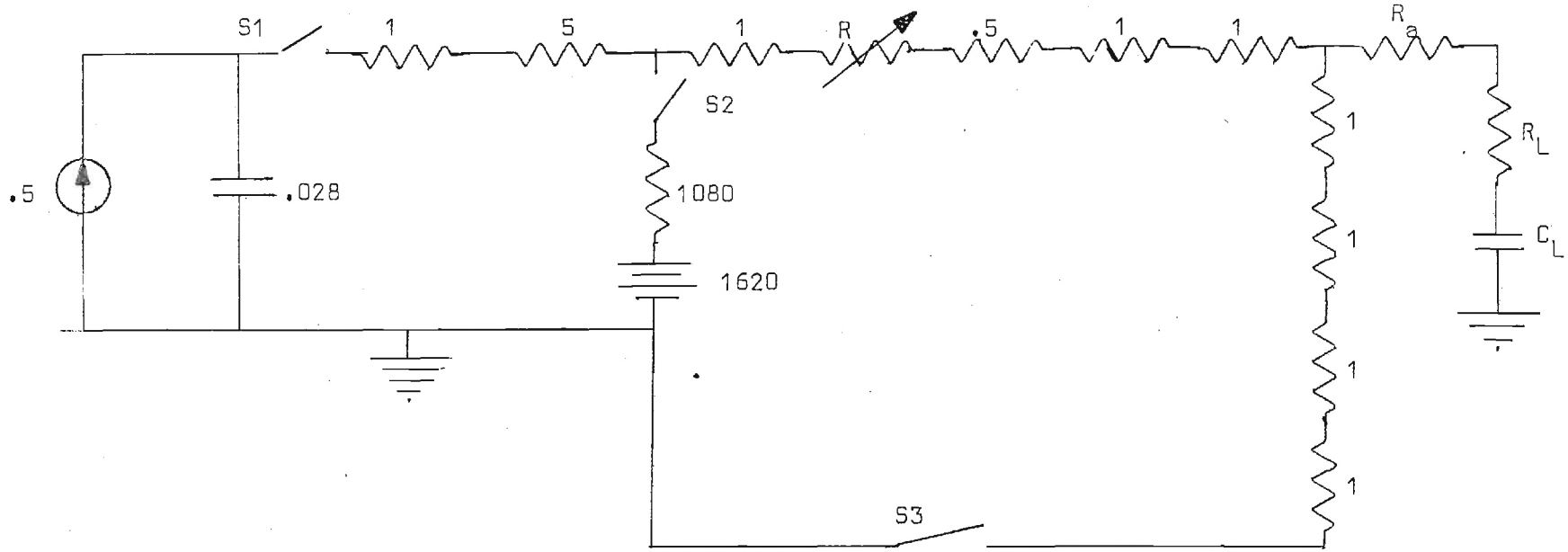


Figure 3.2 Schematic diagram of the respirator during the controlled breathing, open-loop mode of operation.

pump is modelled as a resitance, the value of which is determined from the fact that "the valves are capable of passing 1 liter/sec. with a pressure drop not exceeding 5 cm H_2O" [6]. This yields a resistance of 5 cm H_2O/(liter/sec.). The oxygen solenoid valve will be modelled as a 23 psi (1620 cm H_2O) in series with a resistance determined from the requirement that it pass 1.5 liters/sec. at a pressure of 23 psi. The resulting series resistance value is 1080 cm H_2O/(liter/sec.). The CO_2 scrubber is modelled as a resistance. Again, its exact resistance value is not known; however, as its value is not critical, we will arbitrarily assign it a value of 1 cm H_2O/(liter/sec.). The rate control valve is modelled as a variable resistor. The check valves between the rate control valve and the inhale pressure limit valve and between the exhale flow sensor and the PEEP valve are each modelled as a resistance, the value of which is determined from the requirement that drop in pressure across it at a flow-rate of 3 liter/sec. must be less than 1.5 cm H_2O. This yields a value of 0.5 cm H_2O/(liter/sec.). For this first study we will assume that the setting of the inhale pressure valve is not exceeded; therefore, it is modelled as a resistance, the value of which is determined from the vague statement that the pressure drop across it will be 0.5 cm H_2O at the normal flow-rate (whatever that is). We will assume normal flow-rate is 0.5 liter/sec., which yields a resistance of 1 cm H_2O/(liter/sec.). The inhale and exhale flow sensors and the inhale and exhale filters will each be modelled as a resistance. From the present information, it is impossible to determine the value; therefore, we will arbitrarily assign a value of 1 cm H_2O/(liter/sec.). The patient will be modelled as two resistors in series, one for the airway and the other the lungs, both in series with a compliance. All three will be assigned various values. In this study, we will assume that the PEEP valve is adjusted to 0 cm H_2), and that it can be modelled as the inhale pressure valve, a

pressures	cm of water
compliances	liters/cm of water
resistances	cm of water/(liter/sec)
flows	liters/sec



S1 Inhale Switch
S2 Oxygen switch
S3 Exhale switch

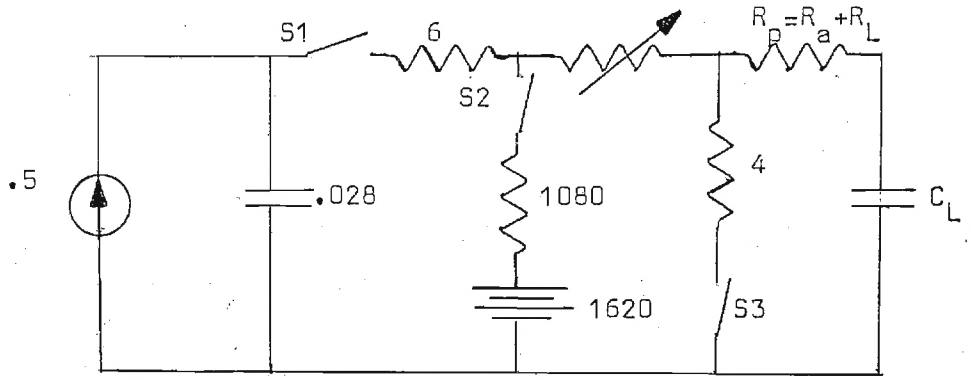
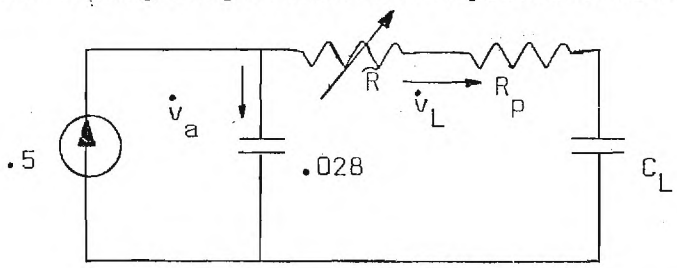


Figure 3.3 Simplified model of the respirator during controlled-open-cycle breathing.

resistance of 1 cm H_2O/(liter/sec.). For simplicity's sake, we will ignore the compliance of the ventilator and its hoses in this study. The resulting simplified model is given in Figure 3.3.

3.2 Analysis of the Effects of the Dynamic Response to the Flowmeter

It is pointed out in [5] that a study should be made to determine how the dynamic response of the flowmeter affects the performance of the respirator. We will do just that for the case stated in Section 3.1--open-cycle, controlled breathing. One other simplification will be made: we will consider breathing on air, no oxygen. Adding the oxygen supply does not appreciably affect the results obtained. With these restrictions, the model during inspiration and expiration becomes



$\tilde{R}$ = 6+ (variable resistance)

Figure 3.4 The Inspiration Model

and

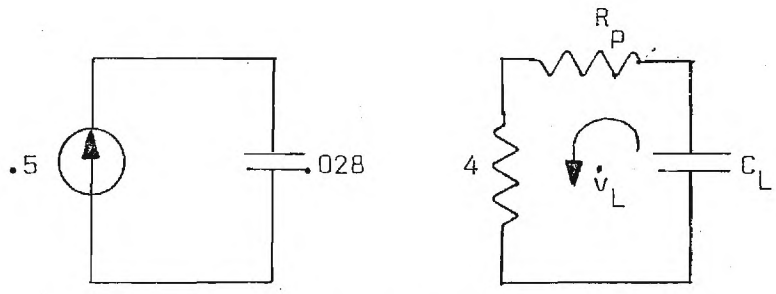


Figure 3.5 The Expiration Model

First, let's consider the expiration mode during which the accumulator is being recharged by the compressor and the lungs are discharging through the exhale circuit. For our model, the colume of air in the accumulator, v_a, is increasing at a constant rate of 0.5 liters/sec. until it reaches 2.0 liters (we are ignoring the compliance of the system; therefore, we are subtracting

the .5 liters added for it); at which time vents open and the accumulator volume remains constant at 2.0 liters. If the accumulator volume does not reach 2.0 liters, it is given by

$$v_a(t) = v_a(t_I) + .5(t-t_I) \tag{3.1}$$

At the same time the patient's lungs are venting according to the equation

$$v_L(t) = v_L(t_I)e^{\frac{-(t-t_I)}{(4+R_p)C_L}} \tag{3.2}$$

where v_L is the deviation volume of gas in the lungs and t_I is the time at which the switchover from inspiration to expiration occurred. Observe that the inspiration model in Figure 3.4 is identical to the model in Figure 2.8; therefore, (2.27) describes the accumulator and lung volumes during inspiration.

$$\begin{bmatrix} v_a(t) \\ v_\ell(t) \end{bmatrix} = \begin{bmatrix} \frac{C_T}{C_L}(1-e^{-t/\tau}) + e^{-t/\tau} & \frac{C_T}{C_L}(1-e^{-t/\tau}) \\ \frac{C_T}{.028}(1-e^{-t/\tau}) & \frac{C_T}{.028}(1-e^{-t/\tau}) + e^{-t/\tau} \end{bmatrix} \begin{bmatrix} v_a(0) \\ v_e(0) \end{bmatrix}$$

$$+ \begin{bmatrix} \frac{C_T}{C_L}[t - \tau(1-e^{-t/\tau})] + \tau(1-e^{-t/\tau}) \\ \frac{C_T}{.028}[t - \tau(1-e^{-t/\tau})] \end{bmatrix} \tag{3.3}$$

where $t = 0$ corresponds to the beginning of inspiration $C_T = .028C_L/(.028+C_L)$, $R_T = \tilde{R} + R_p$, and $\tau = R_T C_T$. First, we will consider one of the cases examined in [7]. We will let $C_L = .05$ liters/cm H_2O and $R_p = 5$ cm H_2O, and will adjust the controls to deliver a tidal volume of 1 liter at 12 cycles/min. with an I/E ratio of 1/4. It is immediately not obvious how to do this. The four second expiration time is no problem; however, obtaining a one

second inspiration time by varying the flow-rate control is quite puzzling. We will have to develop an iterative scheme for determining $\tilde{R}$, or in this case τ.

First, observe that (3.2) yields

$$v_L(0) = v_L(t_I)e^{\frac{-4}{.45}} = .00014v_L(t_I) \approx 0$$

from which we conclude that the lungs completely discharge during the four second expiration period. From (3.1), we conclude that the accumulator will charge completely to two liters during the four second expiration period. For the values chosen for the parameters, (3.3) becomes

$$v_\ell(t_I) = 1.286\ (1 - e^{-t_I/\tau}) + .321[t_I - \tau(1 - e^{-t_I/\tau})]$$

or

$$1 = 1.286(1 - e^{-1/\tau}) + .321[1 - \tau(1 - e^{-1/\tau})] \tag{3.4}$$

Observe that (3.4) can be rearranged to yield

$$e^{-1/\tau} = .472 - .25\tau + .25\tau e^{-1/\tau} = x \tag{3.5}$$

which brings to mind the following iterative scheme for determining the flow-rate setting

1) guess τ
2) evaluate x via $x = .472 - .25\tau + .25\tau e^{-1/\tau}$
3) evaluate τ via $\tau = -1/\ln x$
4) repeat steps 2) and 3) until τ is unchanged.

The iterations converged to $\tau = .883$ seconds, which yields $R_T = \tau/C_T = .883/.018 = 49$, $\tilde{R} = 49 - R_p = 49 - 5 = 44$, or variable resistance $= \tilde{R} - 6 = 38$. After all this, we conclude that the resistance of the variable flow-rate control should be $(38 - 2.5) = 35.5$ cm $H_2O/(\text{liter/sec.})$.

Substituting this value of τ into (3.3) yields the following expression for the volume of gases in the lungs during inspiration.

$$v_{\ell}(t) = 1.003\ (1-e^{-1.13t}) + .321t \tag{3.6}$$

Differentiating (3.6) yields an expression for the actual flow-rate during inspiration.

$$\dot{v}_{\ell}(t) = 1.13\ e^{-1.13t} + .321 \tag{3.7}$$

Now, we are in a position to analyze the effect of the dynamic response of the flowmeter. We will assume that it can be modelled as a simple lag of 20 milliseconds and ignore the bias and scale-factor errors. With these assumptions (2.28) yields the following for the output of the flowmeter.

$$q(t) = 50 \int_0^t e^{-50(t-\sigma)}\ \dot{v}(\sigma)d\sigma \tag{3.8}$$

Substituting the flow-rate equation into (3.8) and integrating yields

$$q(t) = \dot{v}_{\ell}(t) - 1.45e^{-50t} \tag{3.9}$$

The second term on the right side of (3.9) is the error in the flowmeter reading, which at one second is for all practical purposes zero (1.93×10^{-22}). Integrating the second term on the right side of (3.9) yields the error in the indicated tidal volume.

$$v_{ind}(t) - v_{\ell}(t) = -.029\ (1 - e^{-50t}) \tag{3.10}$$

An examination of (3.10) shows that flowmeter lag of 20 milliseconds results in an error in the indicated volume delivered to the patient of .03 liters after $\approx$ 60 milliseconds. Observe that this error results from the flowmeter responding to the initial flow of 1.45 liters/second [see (3.7)]. At the

end of the inspiration period, the tidal volume delivered to the patient will be 1.03 liters--a 3% error. For higher initial flow-rates, this error will be larger.

3.3 Recommendations

A quick analysis has shown that at a setting of (see Figure 3.6)

Tidal Volume	1 liter
Exhale Time	4 seconds
Inhale Rate	Adjusted to make $\frac{I}{E} = \frac{1}{4}$

a 20 millisecond lag (a time constant of 20 milliseconds) in the flowmeter will cause a +3% error in the tidal volume delivered to the patient. Since this error is primarily a function of the initial flow-rates, it is anticipated that the same magnitude error will result in the exhale flowmeter, causing it to yield negative error of the same size--the lag will cause the exhale flowmeter to indicate a smaller volume being exhaled that is actually exhaled--the two errors will tend to cancel each other.

Because of the large errors involved, 3%, it is recommended that the dynamic response effects be studied further at higher flow-rates; however, the initial results indicating that the two flowmeter errors tend to cancel each other is encouraging.

If our understanding is correct, a certain PO_2 of oxygen is obtained by diffusing air with O_2 for a fraction of the inspiration period. This would seem to cause the air that is diffused with the O_2 to have a higher than necessary PO_2 level while the air supplied to the lungs after the O_2 solenoid is closed has a difficiency of O_2. Although the overall tidal volume has the correct PO_2, it seems that the uneven distribution of O_2 would tend to intensify the blood-gas distribution problems mentioned in Section 2.1.

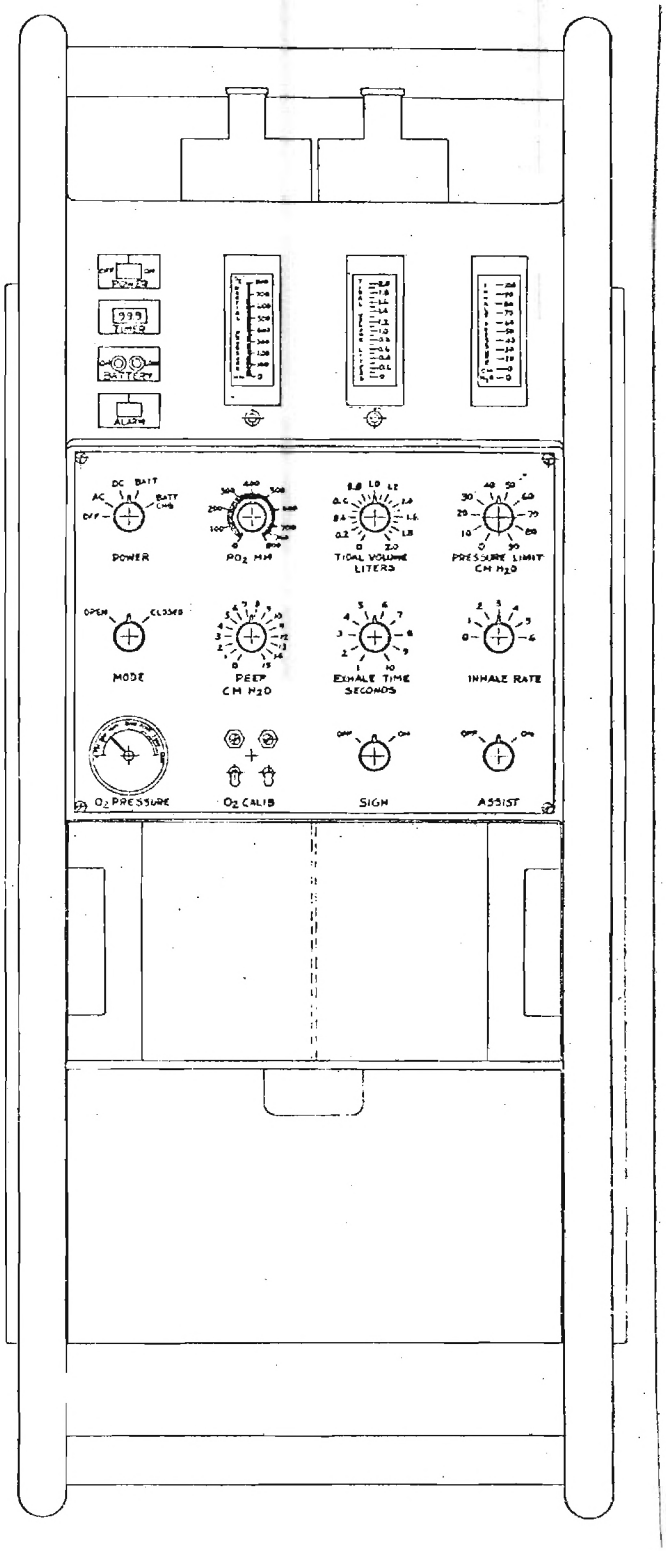


Figure 3.6 The Control Panel

Finally, the difficulty encountered in choosing the flow-rate resistance leads us to believe that the only way anesthesiologist can adjust the respirator to a given I/E ratio is the same way we did--trial and error. This is not a desirable procedure and it should be corrected with urgency.

4. SUMMARY AND SUGGESTIONS FOR FUTURE WORK

A survey has been performed of the literature pertaining to the theory of ventilation and to existing mechanical ventilators. From this survey crude mathematical models have been determined for the various pieces of equipment that comprise a respirators, and those models specialized to the GE-NAVY respirator. The resulting model has been used to show that substantial errors in the tidal volume delivered to the patient occur as a result of the dynamic response of the inhale flowmeter (3% for a maximum flowrate of 1.45 liters/sec.). However, an analysis of the model shows that an error of similar proportions results in determining the volume expired by the patient, and from the standpoint of detecting leaks tends to cancel the error caused by the inhale flowmeter.

It is suggested that these crude models be refined and at the same time more advanced models that include linearities be developed and programmed for the digital computer. The crude models will be used to develop a better feel for the interactions of the equipment comprising the respirator, while the computer models will be used to generate curves and tables which will prove invaluable to NCSL personnel in making decisions pertaining to the respirator.

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APPENDIX A

May 1974

AMERICAN NATIONAL STANDARDS COMMITTEE

ANESTHETIC EQUIPMENT, Z-79

Standards for Anesthesia and Breathing Equipment

Proposed ANSI Standard Specifications

for

BREATHING MACHINES FOR MEDICAL USE
Z-79.7

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FOREWORD

It is the purpose of ANSI Z-79 to specify minimal requirements for the design and construction of breathing machines for medical use. The aim is to ensure that machines designed for this purpose shall be safe and reliably effective and be compatible with other apparatus used in similar applications throughout the world. Since breathing machines have varying capabilities, it is proper that test procedures be developed to provide information concerning their behavior when they are caused to ventilate lungs with different characteristics.

Progress in this field has been rapid and is still continuing at a fast pace. For this reason no attempt has been made in Section 2 to specify the characteristics of an ideal ventilator. It was felt that any such specification would soon be outdated and that it might also inhibit further developments in this field. However, in view of the known effects of ventilator characteristics on the patient's circulatory and respiratory function, it is important that manufacturers shall provide as much information as possible for the prospective purchaser. To facilitate this exchange of information a test procedure has been devised utilizing a model lung with a number of different, but standardized, impedances to ventilator output. It is intended that information derived from tests on this model shall supplement the other information customarily provided by the manufacturer.

BREATHING MACHINES FOR MEDICAL USE

CONTENTS

SECTION 3. HUMIDIFIERS

SECTION 1. GENERAL

1.1 SCOPE

Section 1. of this standard defines the main classes of breathing machine which may be used in medical practice and indicates how these may be further subdivided according to their mode of action.

Section 2. of this standard deals specifically with lung ventilators designed for use on adult, pediatric or neonatal patients.

Section 3. of this standard deals with humidifiers designed for use with lung ventilators.

1.2. CLASSIFICATION AND DEFINITIONS OF TYPES OF BREATHING MACHINES

Class of Equipment	Classification and Definitions
1.2. (1) LUNG VENTILATOR	An automatic device which is connected to the patient's airway and is designed to augment or provide the patient's ventilation.
	A. Types of lung ventilators.
	1. Controller. An apparatus which inflates the patient's lungs independently of the patient's inspiratory effort.
	2. Assistor. A device designed to augment the patient's inspirations synchronously with his inspiratory effort.
	3. Assistor-controller. An apparatus which is designed to function either as an assistor or a controller and which may, in default of the patient's inspiratory effort, automatically function as a controller.
1.2. (2) RESUSCITATOR	A portable device used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate.
	A resuscitator is not conventionally employed with a tracheal tube.
	Resuscitators are classified according to their prime movers as follows:
	(a) Hand powered (b) Gas powered (c) Electrically powered

Auxiliary apparatus and methods for use in emergency situations are classified as follows:

(a) Manual resuscitation
(b) Exhaled air (mouth to mouth or mouth to nose) resuscitation.

1.2.(3) INHALATION THERAPY VENTILATOR

A device which is connected to the patient's airway and is primarily designed to deliver an aerosol and/or augment ventilation.

1.2.(4) EXTERNAL BODY VENTILATOR

A machine designed to augment or replace the patient's ventilation by means of the application of intermittment or alternating pressures to the trunk.

External body ventilators are classified as follows:

(a) Tank or Cabinet. An external body ventilator in which the patient is enclosed to his neck in a rigid airtight chamber.

(b) Cuirass. An external body ventilator in which all or part of the trunk is in an airtight enclosure, forming or incorporating a rigid frame.

(c) Belt. An external body ventilator consisting of a flexible airtight bag wrapped around the patient's trunk. When inflated the bag produces forced expiration followed by inspiration upon deflation.

1.2.(5) ROCKING APPARATUS

A device used to produce or aid ventilation by using the weight of the abdominal contents to move the diaphragm.

1.2.(6) ELECTROSTIMULATOR

An apparatus in which activity of the respiratory musculature is induced by electric impulses acting on the corresponding nerves or muscles.

SECTION 2. LUNG VENTILATORS

2.1. DEFINITIONS RELATED TO THE PERFORMANCE OF LUNG VENTILATORS

For the purposes of this draft recommendation, the following definitions apply:

	TERM	DEFINITION
2.1.(1)	FREQUENCY, VENTILATORY (f)	Breathing cycles per min.
2.1.(2)	TIDAL VOLUME (V_T)	Volume of gas, measured in millilitres entering or leaving the patient or the lung model during the inspiratory or expiratory phase time. The conditions under which gas volumes are measured shall be given.
2.1.(3)	MINUTE VOLUME ($\dot{V}_E$)	Volume of gas in litres expired per minute by the patient.
2.1.(4)	VOLUMETRIC DISPLACEMENT	That volume, expressed in millilitres, passed per cycle, during the inspiratory phase through the patient connection port when the pressures at the intake to the ventilator and at the outlet from the patient connection port are equal to the atmospheric pressure. Such a volume may or may not be equal to the patient's tidal volume.
2.1.(5)	PATIENT SYSTEM	That part of the ventilator gas system through which respired gas travels at respiratory pressures.
2.1.(6)	APPARATUS INTERNAL COMPLIANCE	Volume/pressure relationship (in ml/cmH_2O) of those portions of the patient system which are pressurized during the inspiratory phase time also see clause 2.8.
2.1.(7)	VENTILATOR PRESSURE (P_{vent})	Pressure at a specified point in the ventilator. The conditions under which measurements are made shall be given.
2.1.(8)	AIRWAY PRESSURE (P_{aw})	Pressure at a specified point in the patient's airway. The conditions under which measurements are made shall be given.
2.1.(9)	ALVEOLAR PRESSURE (P_A)	Pressure in the alveoli. In the case of the lung model this is represented by the pressure in the compliance chamber.

2.1.(10)	SUB-ATMOSPHERIC PRESSURE (sub-ambient)	Pressure lower than ambient, developed by the ventilator during the expiratory phase time. (The pressure is normally measured in the delivery hose at a point close to the patient's face (also see 2.1.(7). The sub-atmospheric pressure may be constant throughout the expiratory phase time or it may vary throughout the phase time depending upon the method by which such pressure is generated.)
2.1.(11)	MAXIMUM SAFETY PRESSURE ($P_s max.$)	Highest gauge pressure which can be attained in the patient system during malfunction of the ventilator but with functioning safety mechanisms.
2.1.(12)	MAXIMUM WORKING PRESSURE ($P_w max.$)	Highest gauge pressure which can be attained in the patient system during the inspiratory phase when the ventilator is functioning normally. (This may be limited by a controllable ventilator mechanism to less than $P_s max.$)
2.1.(13)	MINIMUM SAFETY PRESSURE ($P_s min.$)	Highest numerical value of subatmospheric gauge pressue which can be attained in the patient system during malfunction of the ventilator, but with functioning safety mechanisms.
2.1.(14)	MINIMUM WORKING PRESSURE ($P_w min.$)	Highest numerical value of subatmospheric gauge pressure which can be attained in the patient system during the expiratory phase when the ventilator is functioning normally. (This may be limited by a controllable ventilator mechanism to a subatmospheric pressure which is numerically smaller than $P_s min.$)
2.1.(15)	INSPIRATORY TRIGGERING PRESSURE (P_{tr})	The airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.
2.1.(16)	DIFFERENTIAL INSPIRATORY TRIGGERING PRESSURE (ΔP_{tr})	The change in airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.
2.1.(17)	INSPIRATORY TRIGGERING FLOW ($\dot{V}_{tr}$)	The flow which must be generated by the patient at the patient connection port to initiate the ventilator inspiratory phase.
2.1.(18)	INSPIRATORY TRIGGERING VOLUME (V_{tr})	The volume measured at the patient connection port which must be moved by the patient to initiate the ventilator inspiratory phase.

2.1.(19)	INSPIRATORY TRIGGERING RESPONSE TIME (T_{tr})	Time delay between the satisfaction of the inspiratory triggering pressure, and/or flow and/or volume requirements and the start of inspiratory flow.
2.1.(20)	INSPIRATORY RELIEF VALVE	A unidirectional valve designed to admit air to the patient system when the patient inspires spontaneously, and the supply of inspiratory gases from the ventilator is inadequate.
2.1.(21)	INSPIRATORY RELIEF VALVE RESISTANCE	Pressure difference across the inspiratory relief valve at a constant flow of 30 litres per minute in an adult.
2.1.(22)	FAIL-SAFE MECHANISM VENTILATOR	A safety mechanism which permits the patient to breathe air during malfunction of the ventilator.
2.1.(23)	INSPIRATORY PHASE TIME (T_I)	The interval from the start of inspiratory flow to the start of expiratory flow.
2.1.(24)	EXPIRATORY PHASE TIME (T_E)	The interval from the start of expiratory flow to the start of inspiratory flow.
2.1.(25)	INSPIRATORY PAUSE TIME (T_{IP})	The interval from the end of inspiratory flow to the start of expiratory flow.
2.1.(26)	EXPIRATORY PAUSE TIME (T_{EP})	Interval from the end of expiratory flow to the start of inspiratory flow.
2.1.(27)	INSPIRATORY-EXPIRATORY PHASE TIME RATIO	Ratio of the inspiratory phase time to the expiratory phase time.
2.1.(28)	SIGH, VENTILATOR	Deliberate increase in tidal volume for one or more breaths at intervals.
2.1.(29)	WORK, VENTILATOR W	Work performed by the ventilator on the patient expressed in joules. $\int \left(P_{aw} \cdot \dot{V} \right)$
2.1.(30)	POWER, VENTILATOR $\dot{W}$	Rate of work performed by the ventilator on the patient expressed in watts. $P_{aw} \cdot \dot{V}$
2.1.(31)	VENTILATOR EXPIRATORY RESISTANCE	For ventilators in which expiration is not assisted the total resistance to gas flow from the patient connection port, through the expiratory port of the patient system to atmosphere. This is expressed in cm H_2O referred to a flow of 0.5 liters per second. (Suggested test flows are 1 litre per sec. and 0.5. litres per sec. for adults, 0.3 litres per sec. for pediatric model and 0.03 litres per sec. for the neonatal model).

2.1.(32)	TIME CONSTANT	The time in which an exponential decay process is 63% complete.
2.1.(33)	SPIROMETER	A device designed to measure a volume of gas.
2.1.(34)	NEBULIZING HUMIDIFIER	A device designed to add water to the inspired gas in the form of droplets.
2.1.(35)	VAPORIZING HUMIDIFIER	A device ~~designed~~ to add water to the inspired gas in the form of vapor.

Note: Pressure shall be expressed in terms of gauge pressure in units of millibars or cmH_2O.

2.2. LUNG VENTILATOR CHARACTERISTICS (See also Mushin, W.W., Rendell-Baker, L., Thompson, P.W.Napleson, W.W., "Automatic Ventilation of the Lungs", second edition, 1969, Blackwell Scientific Publications Limited, Oxford)

2.2.(1) Modes of operation during the inspiratory or expiratory phase

(a) Flow generator
(b) Pressure generator
(c) Combined flow and pressure generator

2.2.(2) Volume Control

(a) Pressure pre-set
(b) Volume pre-set
  (i) Tidal
  (ii) Minute
(c) Combined

2.2.(3) Cycling Control

(a) Inspiration to Expiration
  (i) Volume
  (ii) Pressure
  (iii) Time
  (iv) Flow
  (v) Combined
  (vi) Manual Overide
  (vii) Other

(b) Expiration to Inspiration
  (i) Pressure
  (ii) Time
  (iii) Flow
  (iv) Combined
  (v) Patient
  (vi) Manual Overide
  (vii) Other

2.2.(4) Types of safety limit

(a) Volume
(b) Pressure
(c) Time
(d) Other

2.2.(5) Types of Pressure Pattern

(a) Positive - atmospheric
(b) Positive - subatmospheric
(c) Positive - positive

2.2.(6) Source of Power

(a) Pneumatic
(b) Electrical
(c) Other

2.2.(7) Power Transmission

(a) Direct
(b) Indirect

2.2.(8) Source of Inspired Gas

(a) Driving Gas
(b) Fresh Gas
(c) Mixed

2.3. LUNG MODEL AND METHOD OF TESTING PERFORMANCE OF LUNG VENTILATORS

2.3.1. Test equipment*

2.3.1.1. Lung model. The lung model is designed to simulate the impedances to ventilator output which may be found in both normal and diseased states. The impedances to ventilator output are lung elastance and airflow resistance: these are simulated in the lung model by a compliance+ and resistance connected in series (Fig. 1). The various combinations of compliances and resistances used in the test procedures are given in Table 1.

2.3.1.2. Compliances. The required compliances are as follows:

C 50	50 ml/cmH_2O
C 20	20 ml/cmH_2O
C 10	10 ml/cmH_2O
C 3	3 ml/cmH_2O
C 1	1 ml/cmH_2O

These compliances shall include the compliances of flow meter, resistance and tubing between the patient connection port and the model compliance. The volume-pressure characteristics of the model compliances shall be measured at ambient pressure and temperature and shall be within ± 5% of the above values throughout a range of gauge pressure changes from -20 to + 100 cmH_2O and throughout a range of inspiratory phase times of 0·1 to 6·0 seconds. Suitable methods of constructing such compliances are described in the appendix. (Appendix A)

2.3.1.3. Resistances. The required resistances are as follows:

	Accuracy ± 20% in flow range	
R5	5 cmH_2O/l/sec	0 - 2·0 l/sec
R 20	20 cmH_2O/l/sec	0 - 1·0 l/sec
R 50	50 cmH_2O/l/sec	0 - 0·5 l/sec
R 200	200 cmH_2O/l/sec	0 - 0·1 l/sec
R 500	500 cmH_2O/l/sec	0 - 0·075 l/sec
R 1000	1000 cmH_2O/l/sec	0 - 0·05 l/sec

The above values relate to dry air at ambient pressure and at 20°C. They include the resistance of the flow-measuring device. Methods of constructing and testing suitable resistances are given in the Appendix A.

*The present suggestions for a lung model do not preclude the development of more sophisticated lung models with the same ranges of compliance and linear or alinear resistances. The lung model serves a similar purpose to those developed by the French Laboratoire National d'Essais. The French lung model system uses parabolic resistances. If these non-linear resistances are used, their characteristics must be stated.

+In clinical practice the elasticity of the lung is usually defined in terms of compliance (volume change per unit pressure change) so that compliance = $\frac{1}{\text{elastance}}$.

Figure 1

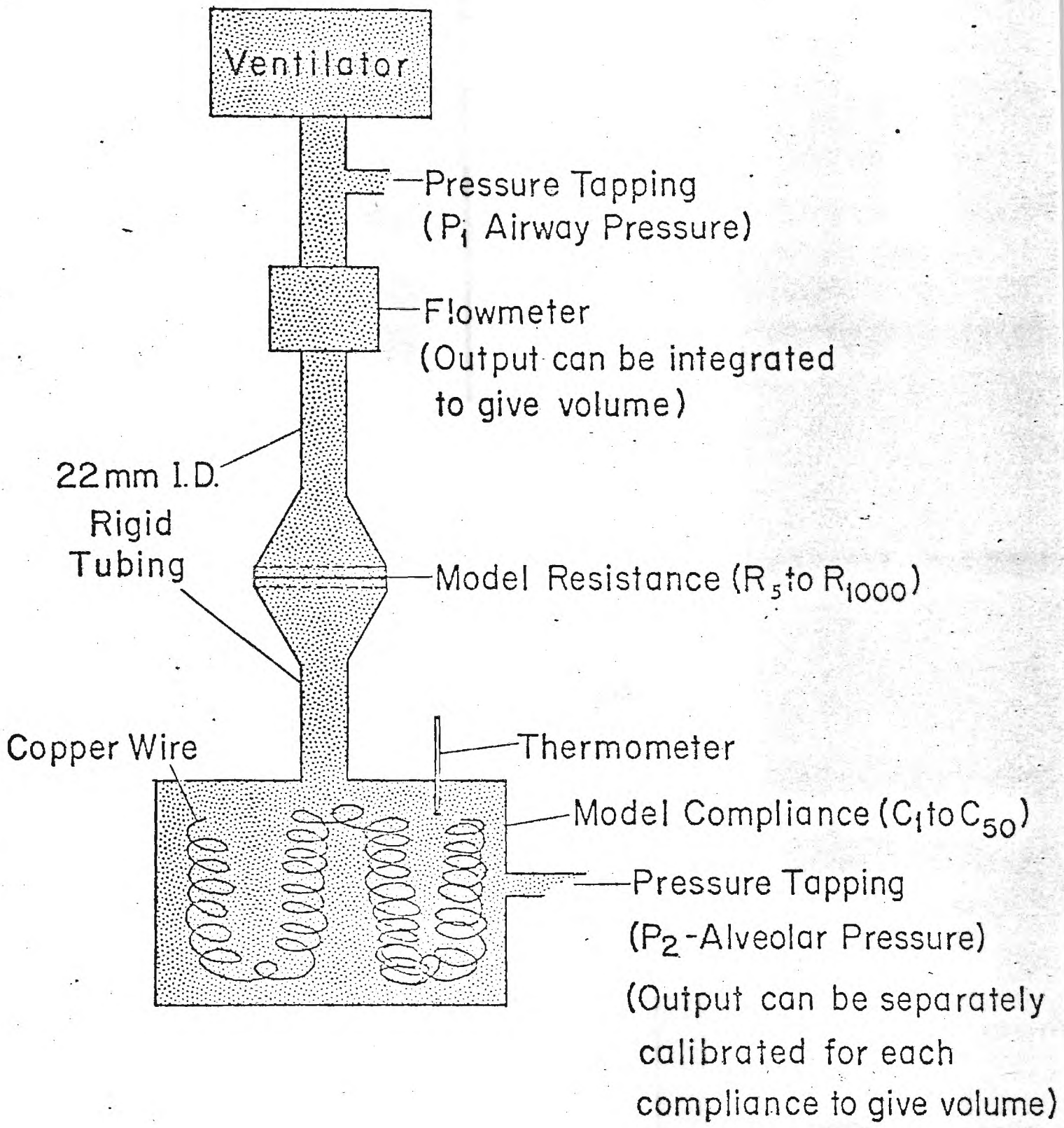

Ventilator
Pressure Tapping
(P_1 Airway Pressure)
Flowmeter
(Output can be integrated
to give volume)
22mm I.D.
Rigid
Tubing
Model Resistance (R_5 to R_{1000})
Copper Wire
Thermometer
Model Compliance (C_1 to C_{50})
Pressure Tapping
(P_2 - Alveolar Pressure)
(Output can be separately
calibrated for each
compliance to give volume)

TABLE 1 - PROCEDURE FOR PERFORMANCE TEST - WAVEFORMS

I : E ratio as close to 1 : 2 as possible - see 2.3.3.2.

Test Number	C	R	V_T ml ± 5%	f ± 5% B.P.M.	For information only T.C. sec.	For information only P_{peak} cmH_2O
Adults						
(1)	50	5	500	20	0.25	12.5
2	50	20	500	20	1.0	20
3	20	5	500	20	0.1	27.5
4	20	20	500	20	0.4	35
Pediatric						
(1)	20	20	300	20	0.4	21
2	20	50	300	20	1.0	30
3	10	20	300	20	0.2	36
4	10	50	300	20	0.5	45
(5)	3	20	50	30	0.06	18.5
6	3	50	50	30	0.15	20.8
7	3	200	50	30	0.6	32
Neonatal						
(1)	3	50	30	30	0.15	12.3
2	3	200	30	30	0.6	19
3	1	50	30	30	0.05	32.3
4	1	200	30	30	0.2	39
5	1	500	30	30	0.5	52.5
6	1	1000	30	30	1.0	75
(7)	1	200	15	60	0.2	24

T.C. = time constant (seconds)

P_{peak} = calculated peak airway pressure for constant flow generators. Additional information relating to peak pressures developed by constant flow generators is given in Appendix B.

The ventilator controls shall be reset to suit the appropriate standard conditions (ringed) before undertaking each subsequent test. Thus the order of recordings obtained on adults would be Test (1), Test 2 (controls unchanged), Test 2 (controls adjusted if necessary), controls reset to satisfy Test (1) conditions, Test 3 (controls unchanged), Test (3) (controls readjusted if necessary) etc.

2.3.2. Measurements. Measurements of pressure, flow and volume shall be made as shown in Fig. 1, and shall be accurate to within ± 2.5% of the reading ± 2.5% of the peak reading in the waveform. Measurements of power and work shall be accurate to within ± 5% of the reading ± 5% of the peak reading. This accuracy shall be maintained at frequencies up to 10 Hz.

The total compliance of the pressure-measuring devices, connecting tubes, flow measuring device and resistance, shall not exceed 4% of the model compliance.

2.3.3. Test procedures. The following tests are type tests to be carried out by the manufacturer on one or more samples of production ventilators with the assurance that the results, which shall be made available to customers, are representative of all production ventilators of that type. These test procedures include one for endurance and two for performance. The endurance test is performed first and the performance tests immediately after. Routine maintenance as specified by the manufacturer may be carried out during these tests, but details of all such maintenance shall be included in the test report.

2.3.3.1. Endurance test. Each tested ventilator (as described in 2.3.3.) shall be tested for endurance in respect of each group of patients for which it is recommende to be employed, i.e. adult, pediatric or neonate. A separate machine may be used for each group or the period of test may be divided equally between groups. The inspiratory : expiratory phase time ratio shall be as close to 1 : 2 as possible and the ventilator run for 2,000 hours against the appropriate conditions:

Group	Minute volume $\dot{V}_E$	Frequency, or nearest possible f	Compliance C	Resistance R
Adult	10	20	50	20
Pediatric	4.5	30	20	50
Neonate	0.8	40	3	200

The test shall be run continously except for necessary maintenance as described in 2.3.3. above.

2.3.3.2. Waveform performance test. The ventilator is connected in turn to each of the compliance and resistance combinations appropriate to its intended sphere of use (i.e. adult, pediatric, neonatal), in the order shown in Table 1. At the beginning of the test, the ventilator controls shall be adjusted to obtain the desired frequency and tidal volume at an inspiratory : expiratory ratio which is as close to 1 : 2 as possible. The ventilator settings required to obtain these conditions shall be recorded. If it is necessary to reset the ventilator controls to match the ventilator to the new set of conditions, this must be noted in the results. In such an event records shall be obtained before and after resetting the ventilator controls. The ventilator shall always be reset to the standard conditions appropriate to a given tidal volume (as indicated in Table 1) before each subsequent test.

All tests shall be performed without a sub-atmospheric phase unless this is an integral feature of the ventilator mechanism.

The following traces shall be recorded during the tests and displayed in the order shown:

(1) Pressure at the patient end of the ventilator tubes (P_1 Fig. 1).

(2) Pressure in the chamber (= alveolar pressure, P_2 Fig. 1).

(3) Flow

(4) Volume

(5) Power - Optional

(6) Work - Optional

If desired, additional recordings may be appended to illustrate special characteristics of the ventilator.

The scale and clarity of the records as reproduced shall be such that a change of 5% of the peak reading can be detected easily. All records shall be inscribed with the appropriate scales, time base, and details of the test. These shall include:

(a) Ambient temperature and pressure, together with the temperature, composition and humidity of the inspired gas.
(b) The nature and dimensions of the breathing tubes connecting the ventilator to the test lung and whether other apparatus (e.g. humidifier, spirometer or water traps) was included in the part of the circuit which is pressurized during inspiration. If such instruments are included the type and position shall be specified. If a humidifier is included it shall be filled to the 'full' water level with gelatin or other relatively non-compressible substance. If this is not practicable, the humidifier shall be replaced with an equivalent compliance and resistance.
(c) All settings of the controls shall be listed if possible.
(d) Any other relevant information (e.g. source and pressure of driving gas, use of special circuits, type of humidifier).

2.3.3.3. Volume performance test. The ventilator is tested against the combinations of compliance (C) and resistance (R) appropriate to its sphere of use:

	C	R	Frequencies
Adult	20	20	10, 15, 20, 30
Pediatric)	10	50)	15, 20, 30, 40
)	3	200)	
Neonatal	1	200	20, 30, 40, 60

The manufacturer shall determine the range of tidal volumes which the ventilator is capable of delivering to the lung at the specified frequencies with an I : E phase time ratio as near 1 : 2 as possible. Further measurements

at different frequencies and with different CR combinations may be included if desired. All results shall be expressed in the form of a table or diagram, e.g. Table 2. The conditions under which the tests are carried out shall be stated (see 2.3.3.2.).

2.4. POWER SOURCES

The ventilator shall continue to function efficiently at any control setting with a variation of not more than ± 10% of minute or tidal volume throughout the range of fluctuation from 105% of the maximum to 90% of the minimum rated voltage and for from 105% of the maximum to 95% of the minimum rated driving gas pressure.

2.5. ACCURACY OF CONTROLS, INDICATIONS AND PRESSURE RELIEF VALVES

2.5.1. It is desirable that when working at nominal power inputs all calibrated controls shall be accurate to within ± 10% of the reading.

2.5.2. Pressure relief valves. Calibrated positive or sub-atmospheric pressure relief valves shall restrict the airway pressure to within ± 5 cm H_2O or ± 20% of the set value (whichever is the greater) for all settings of other controls and in the case of total respiratory obstruction. Transient increases in pressure in the circuit may cause these limits to be exceeded. Valves should be designed to minimize this effect.

2.5.3. Pressure gauges should be accurate to within ± 2.5% of the full scale reading of the gauge in the position of use. An addition error of ± 2.5% of the reading is permitted.

2.5.4. Devices indicating ventilatory frequency shall be accurate to ± 10% of the reading.

2.5.5. As a general rule all other indicators shall be accurate to within ± 10% of the reading.

2.6. SPIROMETER AND OTHER DEVICES FOR INDICATION OF VENTILATOR FUNCTION

2.6.1. Provision shall be made for connection of a spirometer for the measurement of expired gas volume.

2.6.2. Any spirometer shall be accurate to within ± 10% of the reading over the volume and flow rate ranges specified by the manufacturer. The pressure drop with a steady gas flow of 30 l/min shall not exceed 1.0 cm H_2O.

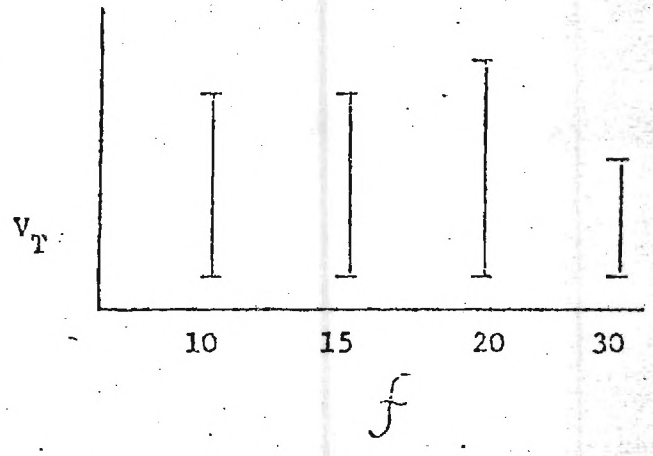
2.6.3. Spirometers shall continue to function within the limits of accuracy delineated in 2.6.2. whatever the humidity and within the temperature range of 10 to 37°C (due allowance having been made for the difference between gas temperature and humidity in the spirometer and the temperature and humidity at which the spirometer was calibrated). Spirometers designed to be positioned close to the patient shall be designed in such a manner that they cannot become obstructed by secretions from the patient.

2.6.4. Spirometers shall be capable of being sterilized (see 2.13.).

TABLE 2

Suggested format of Table and/or diagram used to illustrate volume performance test.

V_T	Frequency			
	10	15	20	30
Max				
Min				



2.7. CHARACTERISTICS OF DELIVERED GAS

2.7.1. The gas temperature at the patient end of the breathing tubes shall in no circumstances exceed 41°C nor fall more than 5°C below ambient.

2.7.2. When ventilators have incorporated an inspiratory gas mixture control, the accuracy of the mean delivered oxygen concentration shall be within ± 10% of the set oxygen concentration throughout the range of pressures, frequencies and tidal volumes of which the ventilator is capable. At a given setting of the ventilator the delivered oxygen percentage shall be stable within ± 3%. If this condition cannot be met then it shall be clearly stated on the machine that "The controls of this ventilator do not permit accurate control of the delivered oxygen concentration".

2.8. EXPIRATORY RESISTANCE

In the absence of expiratory resistors or positive end-expiratory devices the pressure at the patient connection port should not exceed 5 cmH_2O at an expiratory flow of 50 l/min for equipment for adult use, at 15 l/min for pediatric equipment and at 5 l/min for neonatal equipment, when breathing attachments and spirometer as specified by the manufacturer are used. If expiratory assistance is necessary to comply with these requirements it should be stated.

2.9. APPARATUS INTERNAL COMPLIANCE

2.9.1. General. During mechanical ventilation there may be differences between the tidal volume setting, the volume of gas delivered to the lungs and the volume of gas leaving the expiratory limb of the patient system. These differences are due to the addition of fresh gas to the circuit during the inspiratory phase, to compression of gas within the system, to the elasticity of the walls of the positive pressure bellows or connecting tubing and to leaks. This section deals with the volume of gas compressed within the patient system: this depends on the pressure in the system at the end of inspiration and is defined by the internal compliance.

2.9.2. The measurement of internal compliance. In ventilators with a graduated tidal volume scale the internal compliance (Fig. 2) shall be separated into two components:

(1) That part of the patient system within the ventilator from the intake valve to the inspiratory valve (the 'bellows compartment').

(2) That within the tubing from the inspiratory valve to the expiratory valve (the 'tubing compartment').

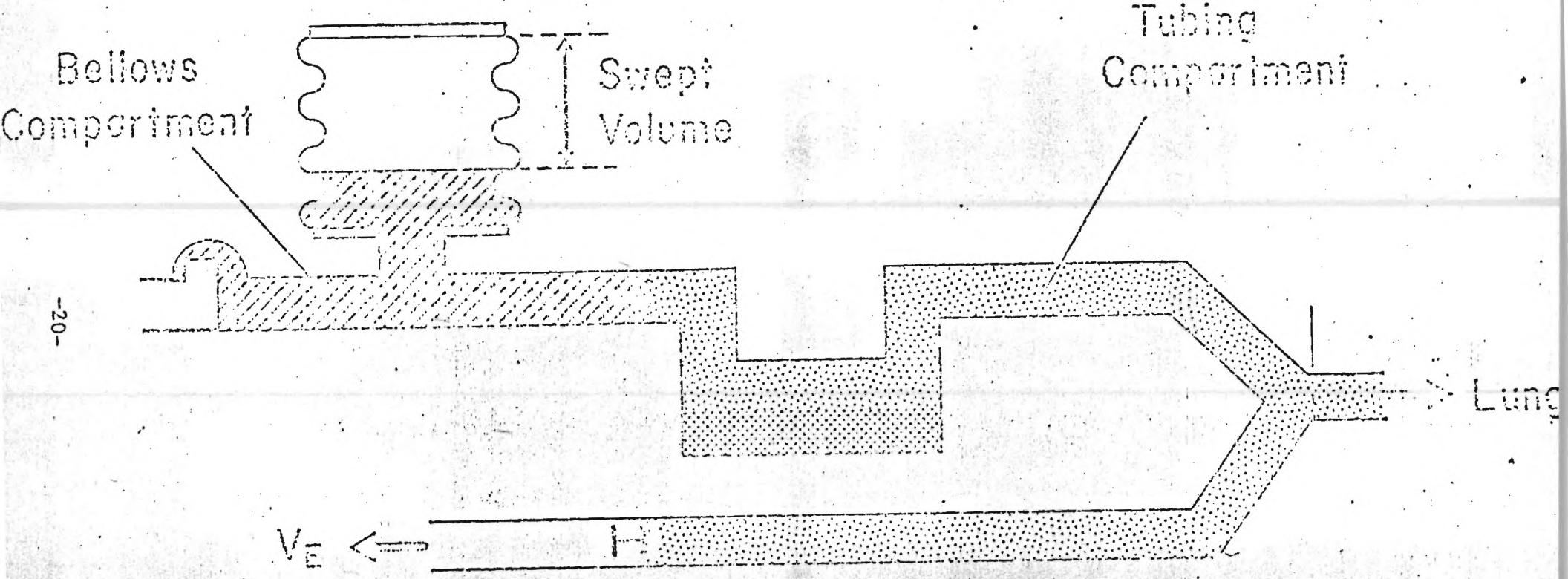
The latter may include the humidifier and water traps if desired. Manufacturer shall state which components are in the system during the test and the probable variations in compliance due to manufacturing tolerances or variations in humidifier water level.

The internal compliance of the bellows compartment results in a difference between the tidal volume setting on the ventilator and the volume of gas passing through the inspiratory valve. In most ventilators this volume of gas remains within the ventilator and does not contribute to the volume of gas measured by a spirometer at the expiratory port.

The internal compliance of the tubing compartment results in the volume of gas recorded at the expiratory port being larger than that delivered to the lungs.

FIGURE II

INTERNAL COMPLIANCE



In some ventilators part of the gas compressed in the bellows compartment discharges to atmosphere through the expiratory valve during expiration. This gas volume contributes to the measured tubing compartment. In other ventilators the expired gas volume may be augmented by a continuous nebulizer gas flow. In either event, manufacturers shall provide a clear statement indicating the likely error in expired gas volume measurement.

2.9.3. The procedures for measuring the internal compliances of these two compartments are given in the Appendix A. The volume/pressure relationship of the two compartments is sometimes alinear. The compliance shall be expressed in the form of a volume/pressure diagram covering a range of end-inspiratory pressures up to 60 cmH_2O or to the maximum safety pressure of the machine, whichever is lower.

2.10. FITTINGS CONNECTING THE ADULT VENTILATOR THE PATIENT AND SPIROMETER

2.10.1. Materials and design. All 22 mm male conical fittings shall be constructed of a rigid material and shall include a groove as standard. Positive locking devices are desirable.

2.10.2. Where the inspiratory/expiratory valve mechanism is integral with the ventilator, all connections leading from the valve mechanism to the patient shall be 22 mm except connections to the patient which shall be 22/15 mm coaxial in accordance with Clause 2.10.1.

The connectors on the inspiratory and expiratory ports shall be grooved 22 mm male cones with groove and shall be preferably mounted with their axes parallel to the floor.

2.10.3. Where the inspiratory/expiratory valve mechanism is not integral with the ventilator it shall nevertheless be considered as being part of the main ventilator mechanism and connections between it and the ventilator shall be non-interchangeable with the 22 mm and 15 mm connections or any other standard connectors. The choice of connections shall be determined by the manufacturer so as to minimize the risk of incorrect assembly of the components, but the connection between the non-integral inspiratory/expiratory valve mechanism and the patient must be 22/15 mm coaxial in accordance with Clause 2.10.2.

2.10.4. All other 22 mm conical connections need not follow a specific male/female sequence except in the case of components of which correct functioning is vital to safety and dependent upon direction of gas flow. Such components shall follow the sequence inlet: female, outlet: male.

2.10.5. If a connector for a bag for manual ventilation is provided on the ventilator this shall face downward and shall be situated away from the connectors for the patient breathing tubes. The bag mount shall be the standard 22 mm male cone with recess and may incorporate a cage support for the bag neck. The connector for the bag shall be clearly marked with a symbol together with the word "bag".

2.10.6. If provision is made for including a spirometer within the patient system (i.e. in the inspiratory or expiratory system or between the patient and the Y-piece) the connection shall be accomplished with standard 22 mm cone and socket joints.

2.10.7. If there is a separate outlet for the spirometer on the breathing tubes or on the machine, and it is intended that the air from the spirometer shall be discharged to atmosphere, then the outlet leading to the spirometer shall be a 30 mm male cone.

2.10.8. If an air inlet is fitted to the ventilator it shall not be a 22 mm, 15 mm or 30 mm male cone and shall be clearly marked as 'Air Inlet'.

2.10.9. If an expired gas outlet (other than an outlet for spirometer) is fitted to the machine, it shall be designed in such a way that it cannot easily be connected to either 22 mm, 15 mm or 30 mm cones or sockets, or to 22 mm internal diameter tubing.

2.11. ALARM SYSTEM

2.11.1. Alarm systems shall provide warning of ventilator malfunction. Alarm systems may provide warning of changes in inspired gas composition or temperature, leaks or obstruction in the breathing system and/or changes in the characteristics of the patient's lung. Such systems may be activated by changes in gas composition or temperature, variations in motive power or changes in pressure, flow or volume in the breathing circuit.

2.11.2. General. An alarm system shall comply with the following:

2.11.2.1. It shall operate independently of any part of the main ventilator mechanism unless it can be shown that failure of the said main mechanism would not impair or prevent the operation of the alarm.

2.11.2.2. The alarm signal shall be preferably audible and visible. Provision shal preferably be made for remote extension. If a remote extension is employed, it shall be so arranged that a failure in the external circuit will not affect the correct functioning of the main alarm system.

2.11.2.3. A simple method of testing the alarm shall be provided.

2.11.2.4. If the alarm is activated by a power failure the alarm shall operate without delay for at least 5 minutes unless reset. All other alarm conditions shall be indicated preferably within 15 seconds and certainly within 30 seconds.

2.11.2.5. A self-resetting delay switch shall be provided to temporarily inactivate the alarm during aspiration of the trachea. This shall inactivate only the auditory alarm.

2.11.2.6. Any portion of the alarm system which is situated within the patient system shall be capable of being sterilized.

2.11.2.7. Indicators used for any visual alarm signal shall be clearly visible under normal operating conditions and shall be suitably protected against mechanical damage. Filament lamps, when used, should be run at not more than 80% of their rated voltage when the equipment is supplied at the maximum voltage appropriate to a specified supply voltage range.

2.11.2.8. If the alarm system is line current operated there shall be an independent alarm to detect mains failure which, if battery operated, must have an automatic charging system or a means of testing the battery.

2.11.2.9. Where batteries only are used they shall be readily accessible and of the long-lasting type. A battery test facility or automatic charging system shall be supplied. The battery container shall not be susceptible to attack by acid or alkali. It shall effectively contain any spillage and if necessary, shall be suitably vented to atmosphere to preclude accumulation of gas evolved during charge or discharge.

2.11.2.10. Where gas-operated alarms are used to indicate a loss of supply pressure from cylinders or pipelines they shall not be dependent on another full cylinder.

2.11.2.11. The manufacturer shall provide detailed instructions for the setting and operation of the alarm mechanism. Adequate operating instructions shall also be marked on the case of the alarm or ventilator.

2.12. HUMIDIFICATION

Humidifiers, if provided, shall comply with the requirements of Section 3.

2.13. METHOD OF DISINFECTION OR STERILIZATION

2.13.1. The manufacturer's recommended methods of disinfection and sterilization shall be provided with each ventilator. Such suggested method of disinfection or sterilization shall be capable of disinfecting or sterilizing all internal and external parts of the lung ventilator without detriment to the ventilator.

2.13.2. The suggested methods of disinfection or sterilization shall ensure that there are no residual substances harmful to the patient's airways or lungs.

2.13.3. The suggested method of disinfection or sterilization shall not affect the performance of the ventilator.

2.13.4. The suggested method of disinfection or sterilization shall be in accordance with the requirements of the relevant national standardizing body.

2.14. ELECTRICAL SAFETY REQUIREMENTS

Appendix D is provided as a guide to basic requirements until such time as an international standard is agreed by IEC/TC 62.

2.15. USE IN HAZARDOUS LOCATIONS

2.15.1. All ventilators that are designed to deliver anesthetic agents and are suitable for use in hazardous anesthetizing locations shall be so marked.

2.15.2. All ventilators designed for use in the presence of explosive anesthetic agents shall be in accordance with the requirements of the relevant national standardizing body. (Guidelines for electrical design for ventilators that are allowed to be used in hazardous locations can be found in Section 2.15 and Appendix D).

2.16. INFORMATION TO BE PROVIDED BY THE MANUFACTURER

In the case of controls the manufacturer shall state the range of adjustment, whether this adjustment is infinitely variable or in stepped intervals and whether the adjustment is dependent or independent of other controls.

(1) Recommended applications (e.g. adult, pediatric, neonatal anesthesia)
(2) Internal compliance
(3) Minute volume range
(4) Tidal volume range
(5) Frequency range
(6) Inspiratory phase time range
(7) Expiratory phase time range
(8) Inspiratory-expiratory phase time ratio range
(9) Ventilator pressure control range
(10) Inspiratory flow range
(11) Inspiratory pressure limit
(12) Inspiratory triggering pressure, flow and volume
(13) Inspiratory triggering response time
(14) Maximum safety pressure
(15) Maximum working pressure
(16) Minimum safety pressure
(17) Minimum working pressure
(18) Sub-atmospheric pressure range
(19) Expiratory resistance or end-expiratory positive pressure range
(20) Sigh characteristics
(21) Inspiratory mixture (range of oxygen concentration and accuracy)
(22) Flowmeter (s) (Function, range and accuracy)
(23) Manual changeover (mode of operation and type of circuit)
(24) Inspiratory relief valve (pressure flow characteristics)
(25) Humidifier and monitors (type and position in circuit)
(26) System pressure gauge

(27) Airway pressure gauge

(28) Spirometer (type and position in circuit)

(29) Alarms

(30) Power source (e.g. air pressure electric current requirements)

(31) Power consumption (watts or l/min)

(32) Dimensions (including floor space for separate stand)

(33) Weight

(34) Method of disinfection or sterilization

(35) Bacterial filter

(36) Fail-safe mechanism

(37) Other pertinent features (e.g. mobility, etc.)

2.17. MARKING

2.17.1. All breathing circuit components in which the direction of gas flow is critical shall be permanently marked in such a way that the intended direction of gas flow is immediately apparent to the operator.

2.17.2. For the purpose of this standard all ventilator system components that contain a valve or valves, the purpose of which is to establish the direction of gas flow are considered to be flow-critical and shall be marked. Examples include Inhalation Check Valves, Exhalation Check Valves and Non-rebreathing Valves.

2.17.3. Where markings are applied to breathing system components in order to indicate the direction of gas flow, the minimum acceptable marking shall consist of at least one headed arrow permanently affixed to the component. Where a component contains more than one check valve, the minimum acceptable marking shall consist of at least one headed arrow indicating the direction of flow through each check valve.

2.17.4. All markings which are applied to breathing system components for the purpose of indicating direction of gas flow are to be located, if possible, so that they will fall in the normal field of view of the operator when the equipment is in use.

2.17.5. Breathing system components which are designed to accommodate gas flow in a specific direction, but which do not contain valves, the purpose of which are to establish gas flow direction, shall be marked. Examples may include humidifiers, moisture traps, carbon dioxide absorbers and filters. The manufacturer shall be responsible for determining if the direction of flow through such components is related to the safety of the patient or the efficiency of the breathing system.

2.17.6. Breathing system components in which the direction of flow is not critical need not be marked to indicate specific flow direction. Examples include masks, breathing tubes, reservoir bags.

2.17.7. Ventilators shall if possible be clearly marked with the following:

(1) Adequate instructions for lubrication and routine maintenance.

(2) If means of hand operation are provided, operating instructions shall be clearly marked on the machine.

(3) Equipment operated by gas shall be marked with the required operating gas pressure.

(4) The relief pressure of non-adjustable safety valves, and the maximum relief pressure of adjustable safety valves, shall be clearly marked adjacent to the relevant equipment.

(5) The maximum volumetric displacement, if it is less than 1400 ml.

(6) Manufacturer's name or trade-mark and country of manufacture.

(7) Inlets and outlets of machine.

(8) Recommended method of sterilization.

(9) Voltage and current requirements.

(10) All connectors for electrical and gas supplies shall be marked with identification labels.

SECTION 3. HUMIDIFIERS FOR USE WITH BREATHING MACHINES

3.1. Design - General.

3.1.1. The construction of the humidifier shall be such that there shall be no danger to the patient, operator or surroundings. It shall be sufficiently robust and corrosion resistant to withstand, without any reduction of safety factors, the mechanical stresses, heating, cooling, anesthetic gases, humidity, sterilizing and disinfecting likely to be encountered.

3.1.2. The internal surfaces of the chamber and gas passages shall be capable of being easily cleaned and sterilized by a readily available technique. The external surfaces of the apparatus shall be designed to facilitate easy cleaning and disinfection.

3.1.3. Access covers which are necessary for the safe use of the apparatus shall be secured by devices which will remain effective after repeated use.

3.1.4. Any control device, other than those to which access is essential during normal use, the operation of which affects the safety of the equipment, shall be inaccessible without the use of a tool.

3.1.5. The resistance of gaseous flow of the humidifier shall not exceed a pressure of 3 cmH_2O under conditions of a steady gaseous flow at a rate of 30 l/minute for adults or 10 l/minute for neonates unless the humidifier is an integral part of the ventilator.

3.1.6. Electrical components shall be designed and positioned so as to reduce the possibility of short circuit in the event of spillage or leakage from the water reservoir.

3.1.7. Adequate precautions shall be taken to drain any condensate away from the patient without adversely affecting the performance of the ventilator.

3.2. Connections. For direction sensitive humidifiers which are not integral with the ventilator, screw-threaded, or non-standard conical connections shall be used. The inlet connection shall be female and the outlet male. The direction of the gas flow shall be permanently indicated on the humidifier.

3.3. Water reservoir.

3.3.1. The water reservoir shall be designed to prevent water from the reservoir entering any other part of the respiratory circuit when the apparatus is tilted 20 degrees out of the horizontal in any direction.

3.3.2. In cases where the level of the water in the reservoir cannot be seen, an easily visible water level indicator shall be provided. This shall also be marked with the maximum and minimum water levels.

3.3.3. The water reservoir in the operating position shall be incapable of being overfilled through the filling orifice.

3.3.4. The filling orifice shall be clearly marked and shall be designed in such a way that it is impossible to connect the filling orifice directly to either 22, 15 or 30 mm cones or sockets, or to 22 mm internal diameter tubing.

3.4. Performance.

3.4.1. Nebulizing humidifiers. The effects of this type of humidifier have not been clearly defined at the present time. It would seem, however, that the following requirements shall be met:

The humidifier shall be capable of delivering a minimum of 33 mg H_2O/l dry gas, and it shall be possible to restrict the total quantity of water to 43 mg H_2O/l dry gas, throughout the range of minute volumes specified in 3.4.2.1.

The droplet size should be in the range 1-5µm. at the patient connection port.

3.4.2. Vaporizing humidifiers (for suggestions as to measurements see Appendix E)

3.4.2.1. Humidity. The humidifier shall be capable of delivering gas with a humidity of not less than 33.0 mg/liter (e.g. a relative humidity of not less than 75% at 37°C) at the patient connection port when the gas has passed through such delivery tubing as is provided or specified by the manufacturer. This humidity shall be maintained when the ambient temperature is as low as 20°C, when the input gas is at a temperature as low as 10°C with a relative humidity of 0 and when the delivered minute volumes extend throughout a range of 5-20 liters per minute for adult use, 2-10 liters per minute for pediatric use and 0.5-3 liters per minute for neonatal use.

3.4.2.2. Temperature limits. The gas temperature at the point of entry to the patient (when tubing as specified in 3.4.2.1. is used) shall be within the range 32-39°C, when the minute volume is maintained at the levels specified in 3.4.2.1. Greater variations in minute volume (such as those produced by temporary disconnection of a pressure preset ventilator during suction) shall never result in a temperature of more than 41°C at the point of entry to the patient.

The temperature of the inspired air shall be limited so that it cannot rise above 41°C. If failure of the normal temperature control could otherwise result in this temperature being exceeded, a separate thermal safety device shall be incorporated and this shall either be of a non-recycling type or shall be arranged to operate an audible and/or visual warning device when the maximum safety temperature (41°C) is reached. If it is possible to change the operating temperature of the safety device, the control shall be accessible only by the use of tools. If the design of the humidifiers is such that the normal temperature limitation is independent of the operation of any thermostat, or similar control device, an audible and/or visual warning device shall be incorporated to indicate when the maximum safety temperature is reached.

3.5. Electrical requirements

3.5.1. General. Electrical equipment for humidifiers shall be in accordance with the relevant requirements of 2.15.

3.5.2. Power supplied for temperature sensors used close to the patient. Appendix D is provided as a guide to basic requirements until such time as an international standard is agreed by IEC/TC 62.

3.6. Information to be provided by the manufacturer. The manufacturer shall provide the purchaser with adequate information on the following:

(1) Basic operating instructions, including instructions for resetting the high temperature cut-out switch if fitted.

(2) The internal compliance (ml/cmH_2O) of the humidifier at the maximum and minimal water levels and the maximal volume of water (liters) shall be marked.

3.7. Marking. The humidifier shall be clearly and permanently marked with the following:

(1) The name or trade mark of the manufacturer.

(2) All connectors and orifices shall be clearly and permanently marked.

(3) Humidifiers which are safe for use in hazardous anesthetizing locations shall be so marked.

(4) Maximum and minimum water levels.

(5) Rated voltage or voltage range.

(6) Rated input expressed in terms of current or wattage.

(7) The letters 'ac', 'ac/dc' or 'dc', whichever are appropriate and, if other than dc, the frequency range.

(8) Identification of type of construction, e.g. double insulated, if appropriate.

APPENDIX A

METHOD OF CONSTRUCTION AND TESTING OF LUNG MODEL

A.1 Compliance

The compliances consist of a number of rigid chambers having the following volumes:

	Compliance	Volume*
C50	50 ml/cm H_2O	51.6 l
C20	20 ml/cm H_2O	20.6 l
C10	10 ml/cm H_2O	10.3 l
C3	3 ml/cm H_2O	3.09 l
C1	1 ml/cm H_2O	1.03 l

The chambers shall ideally be cylindrical and constructed in copper or other material having a high specific heat. The ends shall be dished or reinforced to ensure rigidity. In order to ensure that the compression is isothermal, the chamber shall be filled with copper wool or other material with a large surface area and high specific heat. Approximately 10 kg of copper wool will be required to ensure isothermal conditions with the 50 ml/cm H_2O compliance and this will occupy approximately 2% of the total volume. The diameter of the strands shall be less than 0.05 mm.

To assess whether isothermal conditions have been achieved each compliance shall be tested by recording the pressure response to a forced insufflation of the highest tidal volume delivered in the test procedure given in Table 1. This tidal volume shall be delivered as rapidly as possible by hand compression of a large syringe. The pressure will rise to a peak and decline. The difference in pressure between the peak and equilibrium value shall be less than 5% of the peak pressure.

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*These volumes will give the correct compliance if the container is rigid and contains approximately 2% wire wool by volume when the atmospheric pressure is at its "normal" value of 1013 mbar. Since the compliance of a rigid container is inversely proportional to atmospheric pressure, changes of the latter with the weather (from +4 to -5 %) and with altitude, may require some method of adjusting the volume to keep within the specified tolerance of ± 5%.

A.2 Resistances

Linear resistances can be made of sintered glass or other filter material. If the material suggested below is used it shall be supported by two screens of wire mesh, the edges of the screens being dipped in paraffin wax to provide an airtight seal for the filter material. The cross sectional area of filter material is determined by two thin masks with appropriate sized orifices placed between the screens and filter material and the whole assembly is compressed by two elastomeric rings. For resistances used in adult tests the filter material may be mounted in a container.** For pediatric and neonatal tests where the internal volume is critical smaller mounts may be required.

Resistance	Value (± 20%)	Range of air flow	Material*	Diameter+
R5	5 cm H_2O/l/sec	0 - 2 l/sec	Fram A	27 mm
R20	20 cm H_2O/l/sec	0 - 1 l/sec	Fram B	23 mm
R50	50 cm H_2O/l/sec	0-0.5 l/sec	Millipore	47 mm++
R200	200 cm H_2O/l/sec	0-1.1 l/sec	Millipore	22.5 mm
R500	500 cm H_2O/l/sec	0 - 0.075 l/sec	Millipore	14.2 mm
R1000	1000 cm H_2O/l/sec	0 - 0.05 l/sec	Millipore	10 mm

** For example: Bird in-line water trap (Cat. No. 9993-990)

* Material. Fram A and Fram B. Filter paper supplied courtesy of Fram Corporation, available in small quantities from Department of Anesthesia Research, Rhode Island Hospital, Providence, Rhode Island 02902, U.S.A.

Millipore Type NCWP filter material available in various diameters from the Millipore Corporation, Bedford, Massachusetts 01730, U.S.A Suggested materials NCWP 047 00, 47 mm diam 14 micron pore size.
Screen = Bronze mesh 0.0045 diameter, 100 mesh.
Mask = 5 mil acetate cast film.

+ Because of slight variations in filter paper characteristics or because of differences in construction it may be necessary to make slight changes in diameter to obtain the desired resistance value.

A.3 Connections

For adult tests the ventilator, pneumotachograph, resistances and compliances shall be connected together with minimal lengths of rigid tubing of 22 mm internal diameter. For pediatric and neonatal tests narrower rigid tubing shall be used to ensure that the requirements of 2.3.2. are complied with.

A.4 Measuring apparatus

Flow. A suitable pneumotachograph head for the larger tidal volumes is the Fleisch No. 2 (linear ± 5% 0-250 l/min). For pediatric and neonatal tests a Fleisch No. 1 or 0 head shall be substituted.

Pressure. Transducers of the appropriate sensitivity shall be connected with minimal lengths of rigid tubing of 1-3 mm internal diameter.

Volume. Baseline drift of an integrated flow signal may be counteracted with a breath-by-breath zero reset or by a backing off voltage. An alternative method of determining volume is to calibrate the pressure P2 in terms of volume change.

Power and Work. Power and work may be derived from the relationship power = $P \times \dot{V}$, work = $\int P \times \dot{V}.dxt$

A.5 Suggested methods for measurement of internal compliance.

A.5.1. All methods require that the difference between the volume delivered against zero impedance and the volumes entering the lung and leaving the ventilator system against known impedances be measured at varying end-inspiratory pressures.

All measurements shall be made under dynamic conditions with an I:E phase time ratio of as close to 1:2 as possible and a respiratory rate as near as possible to 20 B.P.M. Measurements of pressure shall be made with a system which is accurate to within ± 2 cmH_2O and which has an adequate dynamic response. Measurements of volume shall be made with a calibrated pneumotachograph system, gas meter or spirometer accurate to within ± 5% of the reading. Meters which are affected by the pattern of flow (Munn and Bai-Ashi 1962, reference 7) are not accurate enough for the measurement unless specially calibrated with the flow pattern being measured.

A.5.2. Tubing Compartment

It is necessary to determine the relationship between the end-inspiratory pressures and the differences in volume between gas leaving the lung and gas leaving the expiratory port on the ventilator.

(1) The ventilator is connected to the C20 compliance and cycled to produce a range of pressures from 0-60 cmH_2O. The differences in volume and end-inspiratory pressures are noted. The volume leaving the ventilator is measured with a spirometer or gas meter (using collection periods of at least 2 minutes) or a pneumotachograph. The volume entering the lung can be calculated from its compliance and the end-inspiratory pressure or the pressure in the compliance chamber can be calibrated directly in terms of volume. The volume entering the lung can also be measured directly by a pneumotachograph.

(2) The lung can be separated from the tubing compartment by a collect valve (Sykes 1969, Brit. J. Anaesth., 41, 189, reference 12). The gas entering the lung is dumped to atmosphere while the gas from the tubing compartment is passed out through the ventilator expiratory port where it can be measured.

(3) A static pressure/volume plot may be determined by blocking the patient system close to the inspiratory and expiratory valves and injecting known volumes of gas from a large syringe into the patient connection port while the pressure is recorded with a side tapping.

A.5.3. Bellows Compartment

It is necessary to measure the difference between the volume delivered against minimal impedance and the volume of gas leaving the expiratory port at various end-inspiratory pressures. (Loh and Chakrabarti, 1971, ref. 5) The difference in volume is then plotted against the end inspiratory pressure to give the compliance curve of the bellows compartment.

(1) The volume delivered against minimal impedance is determined by attaching a pneumotachograph to the patient connection port and setting the ventilator to deliver a fixed volume to the atmosphere. Alternatively the gas volume may be collected into a Douglas bag and measured later by gas meter or spirometer. The ventilator is then connected to a standard compliance and the expired volume from the ventilator is recorded as detailed above. The procedure is repeated at a number of tidal volume settings so that measurements at different end-inspiratory pressures are available.

(2) If the end-inspiratory position of the bellows varies with tidal volume internal compliance will also vary with tidal volume. In this type of ventilator it is necessary to utilize a number of different compliances at each tidal volume in order to produce internal compliance curves for a series of representative tidal volumes.

Note: If fresh gas is added to the circuit during the inspiratory phase the volume of gas delivered to the lungs may vary with fresh gas flow and may exceed the tidal volume indicated on the ventilator. The presence of such a fresh gas flow may make it impossible to measure the bellows and/or tubing compliance. If so, this fact shall be stated.

APPENDIX B: PEAK AIRWAY PRESSURES DEVELOPED BY CONSTANT FLOW GENERATORS IN TESTS SPECIFIED IN TABLE 1

T_C = time constant

$\dot{V}$ = flow rate with $T_I:T_E = 1.2$

P_L = pressure exerted against lung elasticity

P_R = pressure exerted against airway resistance

P_{PEAK} = total pressure developed at end of inspiration

C	R	TC	V_T	f	V_E	$\dot{V}$	P_L	P_R	P_{PEAK}
50	5	0.25	500	20	10	30	10	2.5	12.5
50	20	1.0	500	20	10	30	10	10	20
20	5	0.1	500	20	10	30	25	2.5	27.5
20	20	0.4	500	20	10	30	25	10	35
20	20	0.4	300	20	6	18	15	6	21
20	50	1.0	300	20	6	18	15	15	30
10	20	0.2	300	20	6	18	30	6	36
10	50	0.5	300	20	6	18	30	15	45
3	20	0.06	50	30	1.5	4.5	17	1.5	18.5
3	50	0.15	50	30	1.5	4.5	17	3.8	20.8
3	200	0.6	50	30	1.5	4.5	17	15	32
3	50	0.15	30	30	0.9	2.7	10	2.3	12.3
3	200	0.6	30	30	0.9	2.7	10	9	19
1	50	0.05	30	30	0.9	2.7	30	2.5	32.3
1	200	0.2	30	30	0.9	2.7	30	9	39
1	500	0.5	30	30	0.9	2.7	30	22.5	52.5
1	1000	1.0	30	30	0.9	2.7	30	45	75
1	200	0.2	60	60	0.9	2.7	15	9	24

APPENDIX C: RESPIRATORY DATA ON NORMAL CHILDREN COMPILED FROM AVAILABLE LITERATURE (Provided for information only).

Age	f	V_T	C_T	R_A	Pathological states
	B.P.M.	(ml)	ml/cm H_2O	cm H_2O/l/sec	Infants
1/52	30	17	5	29	RDS C_T (infant - extreme)
1	24	(60)	(16)	(13)	= 0.50 ml/cmH_2O
3	22	(112)	(32)	10	R_A (infant - extreme)
5	20	(130)	44	8	= 350 cmH_2O/l/sec
8	18	(180)	71	6	
12	16	260	91	5	Adult
15	14	360	130	3	Aspiration C_T = 10 ml/cmH_2O
					Asthma R_A = 25 cm H_2O/l/sec

C_T - Total static compliance

R_A = Airway resistance

ELECTRICAL REQUIREMENTS

D.1 Housing. Any motor or other electrical components shall be enclosed in a housing of non-ignitable construction. The enclosure shall be arranged to allow easy access to the motor and other components without deranging the internal electric wiring or airways. The enclosure shall be such that the external surfaces may be easily cleaned and shall prevent the entry of liquid spillage.

D.2 Protection against electric shock. All live parts shall be protected to prevent accidental electric shock. This requirement shall be complied with after the removal of all parts which can be removed without the use of tools. The insulating properties of lacquer, enamel, paper, cotton, oxide film on metal parts, beads and sealing compound, shall not be relied upon to give the required protection against accidental contact with live parts. Parts providing protection against accidental contact with live parts, or parts which are liable to become alive in the event of a defect, shall have adequate mechanical strength and shall not work loose during normal use. Operating spindles of knobs, etc., shall be adequately insulated from live parts. Handles, operating levers, knobs and the like, the shafts of which may become alive in the case of an insulation fault, shall be of insulating material. Where a temperature sensor is used close to the patient, e.g. at the patient end of the inspiratory tube, any electrical power supply for the control circuit shall be "earth free." The voltage source shall not exceed 15 volts and, if derived from a mains voltage supply, the transformer used shall either incorporate an earthed metal screen not inferior to 0.076mm (0.003in) thick cooper completely separating the supply and low voltage windings, or the supply and low voltage windings shall be wound on separate bobbins or if wound on the same bobbin there shall be an imperforate insulating partition between windings which is capable of withstanding the appropriate electric strength test. Other means of achieving isolation are acceptable if the isolation provided is equivalent to that given by the foregoing requirements.

D.3 Motors. Motors shall have sufficient power to enable the ventilator to operate effectively. The motor torque shall be such that the equipment will function correctly when connected to a supply, the voltage of which is 0.8 times the minimum rated voltage.

D.4 Heating. The maximum temperature rise of the component parts when the machine is run continously at maximum rated current for a sufficient time for steady temperature conditions to be achieved, shall not exceed those given below. Any test to establish the temperature rise shall be carried out in an ambient temperature within the range of 25 ± 3°C. Thermal safety devices shall be provided where necessary, to prevent operating temperatures exceeding the specified limiting values under both normal and fault (e.g. locked rotor) conditions.

(1) External parts:

(a) Parts including handles which may be gripped in normal use

(i)	of metal	30°C
(ii)	of porcelain or vitreous material	40°C
(iii)	of other non-metallic material	50°C

(b)	Parts which may be held for short periods only	
	(i) of metal	35°C
	(ii) of porcelain or vitreous material	45°C
	(iii) of other non-metallic material	60°C
(c)	Parts which may be touched inadvertently	60°C
(d)	Contact pins of appliance connectors, terminals, etc.	60°C

(2) Insulation:

(a)	Natural rubber	40°C
(b)	Varnished cambric	60°C
(c)	Butyl rubber	75°C
(d)	Silicone rubber	130°C
(e)	Phenolic mouldings (mineral fillers)	100°C
(f)	Phenolic mouldings (cellulose fillers)	85°C
(g)	Wood	60°C
(h)	Windings and core laminations in contact therewith if the winding insulation is	
	(i) of Class A material (see Note 1)	70°C
	(ii) of Class E material (see Note 1)	85°C

NOTE 1. This classification is in accordance with IEC Publication No. 85.

NOTE 2. If other materials are used they shall not be exposed to temperatures in excess of those which have been proved permissible for these materials.

D.5 Excess current protection. The equipment shall be protected against excessive current by means of a correctly rated fuse or automatic type circuit breaker inserted in each live supply conductor.

D.6 Switches. The equipment shall be provided with a double-pole switch arranged to interrupt each supply conductor. Switches controlling auxiliary circuits may be of the single-pole type. Switches and regulating devices shall be marked and placed so as to clearly indicate their functions. On manually operated switches the on and off positions shall be clearly marked. Switches shall be so located that in normal use they are not exposed to damage.

Knobs, push-buttons and the like, which are intended for manual operation shall either be of insulating material or, if of metal, shall have a grounding (earthing) connection complying with D.8 or should be protected by double or reinforced insulation from live parts.

Switches and similar devices shall be suitably rated for the load controlled and shall comply with a relevant standard or shall be capable of satisfying the following endurance test without mechanical failure or undue pitting or burning of contacts.

Type test. Switches shall be capable of operating 20,000 times at a rate not exceeding 30 times per minute making and breaking the rated current of the appliance while connected to a supply at rated voltage.

D.7 Terminals. The materials, design and proportions of all terminals shall be such that connections made thereto will not slacken or overheat under normal conditions of use. The terminals shall be of sufficient size to accommodate at least the number and diameter of wires appropriate to the appliance current rating and shall ensure that conductors connected thereto are effectively clamped between metal surfaces and that contact pressure shall not be transmitted through any material that is liable to yield or deteriorate in normal use. The pressure from any nut or screw used for clamping a conductor shall not be used to secure any other component.

In pillar type terminals the screws shall be of sufficient length to extend to the far side of the terminal hole and shall be of a diameter approximately equal to that of the hole. The ends of the screws shall be rounded or chamfered to prevent undue damage to the conductors; the side of the hole against which the screw bears shall be smooth and continuous.

A self-tapping screw shall not be used for any form of terminal.

All connections shall be made in such a way that the wires of the conductor are prevented from slipping or spreading at the terminal. Supply and ground (earth) terminals, where used, shall be located in proximity to each other and be designed so that:

(1) Should a wire subsequently break away from its terminal after being correctly fitted, there is no risk of accidental contact between the live parts of opposite polarity or between such parts and accessible metal parts or parts connected thereto.

(2) Excessive dismantling is not necessary to gain access.

(3) The position and arrangement of terminals shall permit easy insertion of conductors and be such that the flexible supply cord may be disconnected and replaced without disturbing internal wiring or connections. The placement of the terminals shall ensure that the specified minimum clearance and creepage distances are maintained when proper connection is made with terminals at full capacity.

(4) Terminals shall not work loose when conductor clamping screws are tightened or loosened.

(5) Special preparation of supply conductors, for example soldering or the use of closed eyelets, is not required in order to prevent slipping or spreading of the conductors at the connection.

(6) There shall be at least three full threads of engagement for terminal screws and nuts when the largest size of conductor is clamped.

For equipment supplied at other than extra low voltage, the line terminal shall be clearly and indelibly marked with the letter L and the neutral terminal with the letter N. The grounding (earthing) terminal shall be adjacent to the supply line terminal and shall be marked with the letter G and the symbol ⏚ ; it shall not be possible to loosen the grounding (earthing) terminal without the aid of a tool. Markings shall be permanent and shall not be placed on screws, washers, or other parts which might be removed when conductors are being connected. If it is desired to use colors for additional markings of the terminals, the International color code (IEC) shall be used. Where more than two supply terminals are provided, the voltage rating shall be clearly and indelibly indicated on or near the terminal. It shall not be possible to change the voltage setting without the use of a tool.

If for equipment supplied at extra low voltage the polarity of the supply is important, then the supply terminals shall be clearly and indelibly marked with the corrected polarity of connection.

D.8 Grounding (earthing). Except for equipment supplied from a safety isolated supply at voltages not exceeding 30 volts dc or 50 volts rms ac with a voltage to ground (earth) not exceeding 30 volts rms ac, or where double insulation is used, accessible metal parts shall be provided with a permanent and reliable ground (earth) continuity path to the main ground (earth) terminal. The requirements of this clause shall not apply to metal parts and screws in or through insulating material and separated from current carrying parts in such a manner that they cannot become alive or come into contact with grounded (earthed) parts.

The resistance shall not exceed 0.1 ohm between any accessible metal part and the grounding (earthing) conductor of the flexible supply cable when measured with a current of 25 amperes flowing and a circuit voltage not exceeding 6 volts. When the test is made from the free end of the flexible cord due allowance can be made for the resistance of the grounding (earthing) conductor in the flexible cord.

In "all insulated" equipment, live parts shall be protected by insulation having adequate mechanical and electrical strength. In double insulated equipment the protection shall consist of functional and protective insulation. Reinforced insulation shall be used only where double insulation is not practicable. Air spacing alone shall not be used for isolating live parts from accessible metal parts unless the positioning of the parts is such that bridging between the live parts and exposed metal is completely precluded.

The body of the grounding (earthing) terminal shall be made of brass or other metal no less resistant to corrosion and shall be such that there is no risk of corrosion resulting from contact with the copper of the grounding (earthing) conductor or of any other metal that is in contact with them.

If the equipment or any external component is connected by a plug and socket device, the grounding (earthing) pin shall make contact before and break contact after the live pins.

D.9 Flexible supply cord, cord anchorage, and storage. Where supplied at other than extra low voltage, the supply connection shall be either a non-detachable flexible cord or an appliance inlet and connector supplied with a flexible cord and having a current rating at least equal to that of the equipment. When an appliance inlet and connector is used the current rating of the cord shall be at least equal to that of the connector.

The flexible cord shall be at least 4.6 meters in length (3 meters in the case of humidifiers unless provision is made for direct electrical connection to the breathing machine when a shorter cord is permissible) the flexible cord shall be either rubber insulated, tough rubber or polychloropreue sheathed or polyvinyl chloride insulated and sheathed and the nominal cross sectional area of the conductors shall not be less then that shown on page 44 Table D 1. Hooks, or a similar device having smooth well rounded surfaces, shall be provided for the storage of the cable.

Equipment with a non-detachable flexible cord shall be provided with a cord anchorage such that the ends of the conductors connected to the terminals are relieved from stress including twisting. There shall not be knots in the cord, tying of the end with string, or any detachable parts which are easily lost. Where the supply cord enters the equipment a properly secured tapered grommet or equivelent device shall be provided to prevent sharp bends at the entry point. The surfaces of the stress relieving and protective device in contact with the supply cord shall be of insulating material.

Compliance with the foregoing requirements shall be checked by inspection and the following test:

The equipment shall be used with its flexible cord, the cord anchorage being used in the normal way. The conductors shall be introduced into the terminals which shall be slightly tightened so that the conductors cannot easily change their position. It shall not then be possible to push the cord further into the equipment. With the equipment at operating temperature, the flexible cord shall be subjected ten times, each for a period of one second, to a pull corresponding to a load of 68 N applied without a jerk. Immediately afterwards the cord shall be subjected to a torque of 0.34 Nm for a period of one minute. During the test there shall be no damage caused to the flexible cord which shall not have been displaced by more than 2 mm and the ends of the conductors shall not have been noticeably displaced in the terminals.

D.10 Internal wiring. Internal wiring between component parts shall be adequately protected and insulated and shall have a fixed protecting layer of insulation appropriate to the maximum working voltage where it passes through metal parts or where it passes over a sharp edge or elsewhere where relative movement would be liable to damage the functional insulation.

burrs, cooling fins, moving parts, etc., which may cause damage to the conductors.

Any plug and socket connector used shall not work loose in normal use. If necessary a locking device shall be incorporated to prevent accidental disconnection.

Internal wiring shall be so fixed that the creepage distances and clearances cannot change in normal use so that they become less than those required in Table D.2.

The color of internal wiring to the supply input terminals shall correspond to that of the supply cable.

D.11 Insulation. Insulating materials shall be suitable as regards resistance to water absorption, rigidity and flammability, and shall meet the electric strength, insulation resistance and leakage tests of Clause D.12.

D.12 Electrical strength insulation resistance and leakage. Immediately, after the ventilator has been kept for 168 hours in a humidity cabinet containing air with a relative humidity maintained between 91 and 95% at a temperature T of approximately 24°C the insulation shall be capable of withstanding the following tests:

The insulation shall be subjected for one minute to an ac voltage of substantially sine-wave form, with a frequency of 60 Hz from a transformer having a capacity of at least 50 V A.

The test voltage shall be applied in accordance with Table D.3. Bulbs with bayonet caps shall be removed and pilot bulbs across supply leads shall be removed or disconnected. For test potentials exceeding 500 V, the test potential shall be increased from 500 V to the final value specified over a period of 10 seconds. No breakdown or short circuit shall occur during the test.

Immediately after the voltage test the insulation resistance shall be measured at 500 V dc. The test shall be made between the points indicated in Table D.3 and between live parts and non-current carrying metal parts, as necessary, to test insulation the breakdown of which could affect the safety of the apparatus. The insulation resistance shall not be less than 10 M ohms.

When operated at the maximum rated voltage, the leakage current (measured in the earth conductor) between the live part of the supply circuit and accessible metal parts shall not exceed 0.5m amps, and the current which can flow to earth from any part of a circuit incorporating a temperature sensitive device used externally to the body of the humidified (eg at the patient end of the inspiratory tube) shall not exceed 0-1m amps. The test to determine this is made with ac except in the case of an appliance for dc only, when dc is used.

D.13 Creepage distances, clearances and distances through insulation. Creepage distances and clearances shall not be less than the relevant values given in Table D.2.

D.14 Separation of electrical components from oxygen and the breathing system. Care shall be taken that components carrying oxygen are separated sufficiently from electrical components to avoid the risk of fire under normal or fault conditions. Electrical components liable to overheat under fault conditions shall not be so placed that they can be surrounded by an oxygen enriched atmosphere nor shall such components be placed in any airway of the patient's breathing system.

D.15 Radio interference. The apparatus shall not cause undue radio interference.

D.16. Additional requirements for equipment which may be used in a zone of risk associated with the use of flammable anesthetics.

D.16.1. General. Care shall be taken that flammable anesthetic gas mixtures do not reach electrical components liable to spark, or liable to reach the ignition temperature of such mixtures, either under normal or fault conditions.

Because of the relatively rapid dilution of flammable anesthetic gas mixtures escaping from anesthetic apparatus into the atmosphere it is often possible to achieve safe working conditions by spacing electrical apparatus, which might otherwise be an ignition hazard, away from the anesthetic apparatus and for this purpose a spacing of at least 0.25 meters from any part of the breathing circuit shall be adequate.

With lung ventilators in which flammable gas mixtures may be enclosed in the breathing system it may not be possible to achieve such spacing and in this case the following additional precautions shall be taken.

D.16.2. Enclosure. Electrical components liable to spark or reach a temperature exceeding 150°C either under normal or fault conditions shall be enclosed either:

(1) in a flameproof or explosion proof enclosure.

or (2) in a case or cases of reasonably gas-tight construction having gaskets of adequate performance and flexibility between the joining surfaces of any removeable cover. The gaskets shall be easily replaceable and each gasket shall be retained on one of the joining surfaces.

The enclosure shall be constructed so that it will remain effective under normal conditions of handling. The construction shall be such that the omission or fracture of any one screw or bolt used in the enclosure and accessible from outside the enclosure will not destroy the gas-tightness of the enclosure, and it shall be capable of withstanding, without leakage of more than 5% of the enclosed volume, a differential air pressure of at least 100 mm Hg with respect to atmospheric pressure for a period of 30 minutes.

Extensive dismantling shall not be necessary to secure access to these parts which it may be necessary to replace or adjust during normal servicing.

The enclosure shall be capable of withstanding, without damage or hazard, any self generated internal air pressure and under no normal or fault conditions shall the materials or components enclosed give off flammable vapors.

or (3) in a hermetically sealed enclosure of incombustible construction.

TABLE D 1

Rated current of appliance	Nominal cross sectional area
A	mm
Up to and including 6	0.75
Over 6, up to and including 10	1
Over 10, up to and including 16	1.5

TABLE D 2: CREEPAGE DISTANCES, CLEARANCES AND DISTANCES THROUGH INSULATION

		Distance mm
(1)	Creepage distances:	
(a)	Between live parts of different polarity	2
(b)	Between live parts and other metal parts over functional insulation protected against the deposition of dirt or moisture; if of ceramic material, pure mica and the like	2
	If of other material	3
	Over functional insulation not protected against the deposition of dirt or moisture	4
	Over reinforced insulation	8
(c)	Between metal parts separated by supplementary (protective) insulation	4
(d)	Between live parts and metal foil in intimate contact with exposed insulating surfaces and between ungrounded accessible metal parts and the outer surface of functional insulation	6
(e)	Between lacquered or enamelled windings and metal parts separated from live parts by functional insulation only	2
	By reinforced insulation	
(f)	Between live parts of the supply circuit and conductors for any extra low voltage circuit directly incorporating a temperature sensitive device used externally to the body of the humidifier, e.g. at the patient end of the inspiratory tube	25
(2)	Clearances:	
(a)	Between live parts of different polarity if protected against the deposition of dirt or moisture	2
	If not protected against the deposition of dirt or moisture	2
(b)	Between live parts and other metal parts separated by functional insulation:	3
	if protected against the deposition of dirt or moisture	2
	if not protected against the deposition of dirt or moisture	3
	Separated by reinforced insulation	8

TABLE D 2 (Cont'd.)

	Distance mm
(2) Clearances (cont'd.)	
(c) Between metal parts separated by supplementary (protective) insulation	4
(d) Between live parts and metal foil in intimate contact with exposed insulating surfaces and between ungrounded accessible metal parts and the outer surface of functional insulation.	6
(e) Between lacquered or enamelled windings and metal parts separated from live parts by functional insulation only	2
by reinforced insulation	6
(f) Between live parts of the supply circuit and conductors for any extra low voltage circuit directly incorporating a temperature sensitive device used externally to the body of the humidifier, e.g. at the patient end of the inspiratory tube	25
(3) Distances through insulation*:	
(a) Between metal parts separated by protective insulation	1
(b) Between metal parts separated by reinforced insulation	2

*These values do not apply to components such as switches, sockets, etc. which comply with a relevant Standard.
These items may consist of a layer of insulation which passes the electric strength test plus one or more air gaps. They may be reduced if two or more separate layers of insulation are used, provided that each layer passes the appropriate electric strength test for the whole.

TABLE D 3: TABLE OF TEST VOLTAGES

Point of application	Test voltage
	V
(1) Between live parts of different polarity and between live parts and other metal parts which are normally grounded	
(a) Where maximum potential difference cannot exceed 30 V	500
(b) Where maximum potential difference is more than 30 V but does not exceed 250 V	1500
(2) Between live parts and metal foil arranged in intimate contact with exposed insulating surfaces or accessible metal parts not normally grounded (where maximum potential difference does not exceed 30V, (1) (a) applied)	4000
NOTE. Contacts and contact carrying members of micro gap switches may be excluded provided that they will withstand a test voltage of 750 V.	
(3) Between supply lines and extra low voltage windings of any transformer used for supply to any circuit incorporating a temperature sensitive device used externally to the body of the humidifier, e.g. at the patient end of the inspiratory tube	4000

APPENDIX B

Summary of Standards

Consideration of the risk current limits for an electromedical device must be predicted on the most hazardous usage situation. The current addressed here is leakage current as defined and explained on pages 1 and 2. In order to classify equipments by hazard levels risk classes and their associated allowable limits are defined on pages 3-5 for Ref. 1 and 5-6 for Ref. 2. Pages 6-10 outline the standards tests for Ref. 2 and 11-13 for Ref. 1. The remaining pages address design qualities that should be the goal of well-designed safe medical instrumentation.

Briefly, the limits on leakage current for devices not having direct electrode contact with the patient but are used in situations where a patient may have a pacemaker on the myocardium are

100 microamperes	NFPA 76B-T, 30522, p. 11
10 microamperes	AAMI Standard, 4.8.1, p. 6

Briefly, the important cord/plug requirements are

1. must meet leakage requirements
2. must meet so type cable NFPA-70, 400-11, p.23
3. plug must meet 410-SS NFPA-20, p.23
   (Hubbell plug #23034 or equivalent) p. 19

General

1013. The major hazard of concern in this standard is electric shock resulting from failure in normally safe electric systems or appliances. The defects may be in the wiring, a faulty component, deteriorated insulation, mechanical abuse, or improper application to the patient. The shock hazard is enhanced by circumstances peculiar to a hospital.

Leakage Current — Any current, including capacitively coupled current, not intended to be applied to a patient but which may be conveyed from exposed metal parts of an appliance to ground or to other accessible parts of an appliance.

Small electric currents can be demonstrated in conductors which are connected between ground and the exposed metal surfaces of conventional power line operated electric appliances. They result from the capacitive coupling and resistive leakage between the energized conductors and metal housing of appliances. Larger currents would flow in the event of a defect in the insulation which permits live conductors to contact the metal housing. A protective grounding system limits the rise above ground in electric potential of the metal housing of the device while providing a return circuit to activate overcurrent protective devices, such as fuses or circuit breakers, when faults do occur.

10302. Grounding. Grounding is a basic protection against fault and leakage currents in the exposed metal case of an appliance. The grounding conductor (green insulation) in the power cord and the grounding prong of the attachment plug provide a path which returns these hazardous currents harmlessly to the source rather than having them return entirely through the patient. The grounding conductor also facilitates the operation of overcurrent protective devices under ground fault conditions.

Modern practice adds a grounding wire to the appliance power cord, as shown in Fig. A–2031–2. The total leakage current (i_{leak}) now divides between the grounding wire (i_1) and the patient (i_2). If the patient impedance is 500 ohms (a currently accepted value) and if the grounding circuit resistance from the chassis through the grounding wire and back to the service entrance ground is 1 ohm, the patient will carry only 1/500 of the total leakage current provided the ground-to-ground potential difference is ignored.

The total leakage current could then be as great as 5 milliamperes before it contributed 10 microamperes to the patient. However, the potential difference between the Patient Grounding Point and service entrance ground cannot be ignored. This potential difference is applied directly to the appliance chassis by the grounding conductor which was added to bypass the leakage current. Even if the appliance in question contributes no leakage current, the potential of the chassis will be raised with respect to the Patient Grounding Point. Ground fault currents due to defects remote from the patient vicinity typically contribute to the ground-to-ground potential difference just discussed.

For a patient impedance of 500 ohms and a current limit of 10 microamperes, the maximum permissible potential difference between the appliance chassis and Patient Grounding Point is only 5 millivolts.

It is impossible to prevent some coupling of the patient's body to ground by capacitance or accidental contact with nearby grounded objects. Indeed, a direct connection via a grounded surface electrode which is part of an instrumentation system may be required. The external end of the conductor leading into the heart could accidentally make contact with nearby conductive surfaces in the patient vicinity. The object to which the patient's body is most likely to be grounded will be called the Patient Reference Ground.

Plumbing and other building metal, provide fortuitous conductive paths which interconnect the Patient Reference Ground and the service entrance ground to which the electric distribution system is bonded. Furthermore, because of currents from a variety of uncontrolled sources that may flow in these fortuitous conductive paths, there can be substantial differences in potential between these two "grounds".

Equipment classification

1.0 Scope

This AAMI Standard describes the minimum recommended specifications and design considerations for the safety of patient, subject, and operator of electromedical apparatus. This standard is applicable only to diagnostic, therapeutic, research, and auxiliary apparatus that:

a. is electrically operated, and
b. is designed primarily for professional use in clinical or research medical facilities such as hospitals, clinics, laboratories, or doctors' offices, and/or
c. may contact a patient thereof, either intentionally or casually.

The object of part 1 of this standard is to define the minimum safety considerations relative to the risk currents that may flow to or from such apparatus.

102. Levels of Susceptibility to Electric Shock.

1021. Physiologic Effects of Electricity — Shock Hazard. The susceptibility of humans and other animals to electric shock is not sharply defined. Rather, there is a broad spectrum of physiologic effects for each individual over a range of exposures and currents, and for a given current level over a range of population. Details of these classes of effects are given in the references, Appendix B.

The nonthermal effects of electricity involve sensation, i.e., feeling the current as increasingly painful; neural stimulation; involuntary muscular contraction; the inability to release muscular contraction (duration tetany or "letgo" current). Stimulation of certain nerves may be lethal; that of the vagus may result in cardiac arrest; that of the respiratory center may cause respiratory paralysis. Direct stimulation of the heart may cause fibrillation.

Individuals differ in their response to electricity. The range of response is increased when the population includes sick people. In this standard the values of current for various hazard levels are based on statistical consideration of the observed data. For example, one-half percentile values are given for lower limits in Table 1022A. A large factor of safety must be included in design criteria to accommodate the broad spectrum of susceptibilities and undetermined factors.

1022. Classes of Hazard Levels. Tables 1022A and 1022B divide patient susceptibility to electricity into three classes primarily on the basis of contact with electric conductors in the environment.

10221. Risk I comprises patients without debilitating disease who are reasonably alert and mobile, and who are minimally exposed to electric monitoring or therapeutic appliances. Their hazard level is similar to that of the general public but somewhat increased, since they are likely to be in electric beds, have electric appliances such as lamps, radios, and call buttons close at hand and may be wet. Sick patients are less alert than usual and therefore prone to ill-advised actions. The contact of Risk I patients with electric conductors is likely to be external, accidental, temporary

and easily interrupted. The occupational hazard of hospital personnel is comparable to Risk I.

The minimum hazardous current levels for external contacts range from the order of 4.5 milliamperes for "let go" level to 80 milliamperes which could induce ventricular fibrillation. These values are for 60 Hz current. (*See Table 1022A and 1022B.*) With a typical patient resistance of 1,000 ohms, 4.5 to 80 volts are needed to produce these currents. In the range of 1 to 4.5 milliampere or less, there may be a disturbing sensation.

The basic method of protection for Risk I is to reduce the possible contact with electric power by enclosing or insulating energized conductors, and by grounding exposed metal of electric appliances. The insulation of exposed conductive surfaces in the patient vicinity provides additional protection.

The design goal maximum leakage current in the grounding wire for each appliance used on such patients is 500 microamperes. Under normal operating conditions this leakage current is diverted from the patient by grounding conductors.

10222. Risk II includes patients who are critically ill, less alert, perhaps obtunded, more likely to be monitored or connected to several therapeutic appliances, and subject to more manipulation by attendants. They are likely to have intentional conductive contacts, external or subcutaneous, that are firmly attached for long periods of time, and they are more likely to be wet. Because of their disease or medication, they may be subject to ventricular fibrillation at lower current levels. The inability of the patient to separate himself from his contacts and the low contact resistance make painful and paralyzing currents more likely to occur. Voltages from one to 10V may cause such currents.

For Risk II patients, the basic protection is voltage reduction by means of an equipotential environment possibly augmented by insulation of the ungrounded exposed metal in the environment. Grounding circuit continuity testing can ensure the maintenance of grounding integrity. Appliances must be designed to stricter criteria; more frequent and intensive inspection and testing is required than with Risk I patients. Ground fault circuit interrupters or isolated power systems enhance protection against ground fault currents.

The design goal maximum leakage current in the grounding conductor for each appliance for Risk II patients is 50 microamperes. This applies particularly to appliances which are intimately associated with the patient, with intentional conductive contacts, such as electrodes, endoscopes, etc. Leakage currents in such patient contact (leads) shall be less than 50 μA. Under normal conditions even this current is diverted from the patient by the appliance grounding conductor. Additional protective mechanisms such as an equipotential environment, insulation of exposed metal and use of current limiters further reduce the possible hazard.

10223. Risk III patients have a direct low impedance electrical connection to the conduction system of the heart. This may be a transvenous or intrathoracic wire such as a pacing catheter, or a nonconductive catheter filled with conductive liquid or other device deliberately introduced for diagnostic, therapeutic, or investigative purpose. The increased electric hazard for Risk III patients results from the high current density at the tip of the externalized conductor when electricity is inadvertently applied to its exposed end. Current applied to the endocardium has been shown to cause fibrillation with as little as 20 microamperes at 60 Hz in the dog. (*See A10223.*) It is estimated that an equal current may cause fibrillation in the human. Data obtained during open heart surgery indicate that minimum currents of about 200 microamperes applied to the epicardium are required to cause fibrillation. The design goal of 10 microamperes maximum current to the heart muscle probably provides a safety factor of at least two and perhaps ten.

It is difficult to provide an equipotential environment to protect against a 10 microampere hazard level under fault condition. The basic protection for cardiac catheterized patients is insulation of the exposed catheter terminal. Risk III patients require the same protection as Risk II patients, plus an equipotential or insulated environment or fault current limitation for ground fault protection to complement insulation of the catheter terminal.

For skin contact, current levels similar to Risk II patients are critical.

10304. Patient Current Paths

103041. Accidental Current Paths. Electric current will flow through a patient when he is connected purposely or accidentally to two energized conductors at different electric potentials. Instead of an obvious electrode or wire, one conductor may be the metal sheath of an instrument or a grounded metal surface, such as the bed, in contact with the patient.

Poorly designed, improperly constructed, or faultily maintained appliances may fail, imposing a hazardous potential on patients' leads. The metal cabinet of an appliance may not be at ground potential if there is a fault between the power conductor and the cabinet or the grounding path has insufficiently low impedance. Incorrect polarity of the plug or receptacle may impose line voltage on the cabinet of an appliance. Incorrect wiring of the appliance power cord has been a common error.

2014. Patient Vicinity. The significant location in which measures shall be taken to reduce the hazard of electric shock in the patient vicinity. The patient vicinity is a space with surfaces likely to be contacted by the patient or an attendant who can touch him. This represents the surfaces within approximately 6 feet of the reach of the patient wherever he may be.

2.3 *Apparatus Type Designation*

The following apparatus type designations are established:

2.3.1 Type "A"

Apparatus to be used on or within the reach of patients having devices with a terminal end introduced into the thorax and conductively connected to a point accessible outside of the body.

2.3.2. Type "B"

Apparatus used only on patients not having devices with a terminal end introduced into the thorax and conductively connected to a point accessible outside the body.

3.0 Definitions of Terms

3.1 *Electromedical Apparatus*

Any instrument, equipment, system, or device that directly or indirectly uses electricity for any medical purpose. Also included are all parts that are connected to such equipment, and all additional apparatus which is to be connected to the equipment and which is requisite for the normal use of the equipment, including the associated patient wiring or cables.

3.2 *Individual Apparatus Risk Current*

Individual apparatus risk current is any nontherapeutic current that may flow through the patient, medical staff, or bystander as a result of the use of an individual electromedical apparatus. Excluded are currents used for therapeutic purposes. *Examples* of risk currents include: leakage currents, surge currents; fault currents, or measurement currents.

3.3 *Composite Risk Current*

The composite risk current is the total current that may flow through the patient, medical staff, or bystander; that is, the sum of the individual apparatus risk currents of all of the apparatus in use.

AAMI Standard Tests

4.8.1 *Low Frequency (d-c to 1 KHz) Risk Current Limits*

In the pass band of d-c to 1 KHz, the absolute maximum nontransient risk current shall not exceed 10 μa, RMS, for type A apparatus and shall not exceed 500 μa RMS for type B apparatus.

Type A: 10 μa, RMS.
Type B: 500 μa, RMS.

4.8.3 *Transient Risk Current Limits*

For type A Equipment, any pulse or transient risk current, measured as described in section 4.10, shall not exceed a 100 μa peak, or 200 μa peak to peak decaying to 14.0 μa peak or 28.0 μa peak to peak within 5 msec.

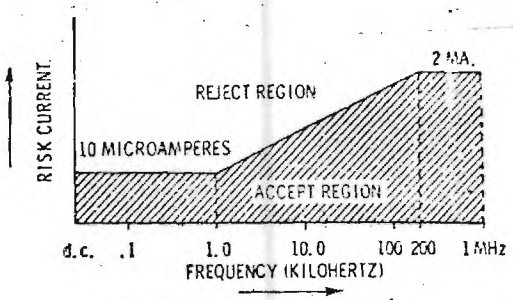

FIG. 1. Type A risk current limits.

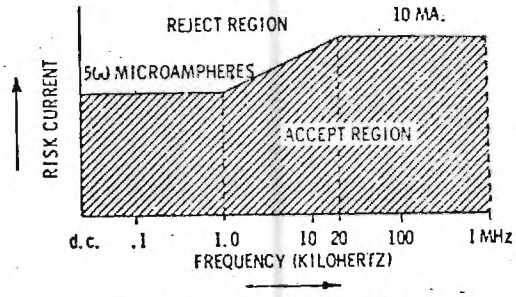

FIG. 2. Type B risk current limits.

4.10 *Risk Current Measurements*

The risk currents of individual electromedical apparatus shall be measured by the methods described in this section. The risk current shall be first investigated using an oscilloscope. Essentially sinusoidal, complex sinusoidal, or rectangular repetitive currents may be measured using any commercial RMS indicating meter. Transients and repetitive spikes shall be measured using an oscilloscope.

When multiple risk currents of various frequency and phase relationships are present, the total risk current shall be considered to be the instantaneous sum of the individual currents.

4.10.1 *Test Conditions*

The risk current of an apparatus shall be considered to be the greatest of the following:

a. For type A or B apparatus: the risk current flowing between any patient connection and power ground, or between chassis and power ground, or between combinations of patient connections (Fig. 6)

1. when electricity supply polarity is normal or reversed and ground is intact;
2. when electricity supply polarity is normal or reversed, and ground is open;
3. during the operation of all accessible controls, with all controls operated in any possible pattern or combination; and
4. when any internal power supply or supplies fails in an open or shorted mode.

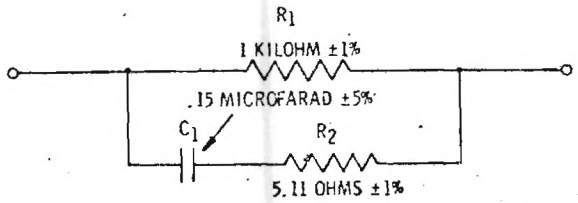

FIG. 3. AAMI standard test load, type A.

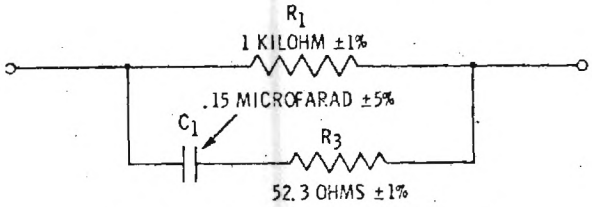

FIG. 4. AAMI standard test load, type B.

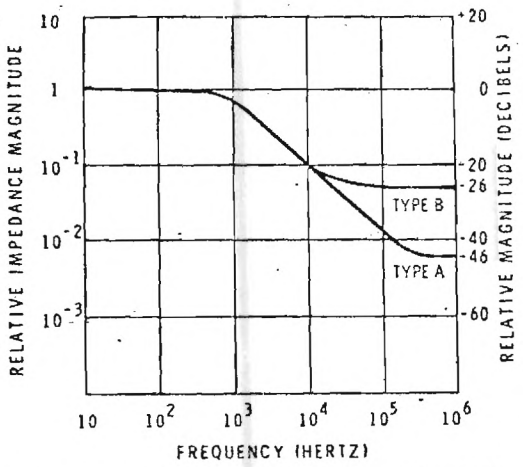

FIG. 5. Impedance-frequency characteristics of AAMI standard test load.

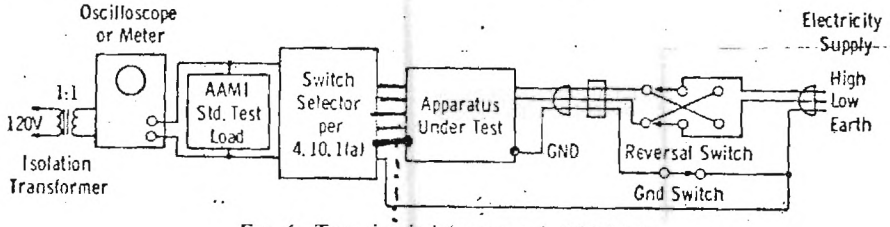

FIG. 6. Test circuit 1 (paragraph 4.10.1 (a)).

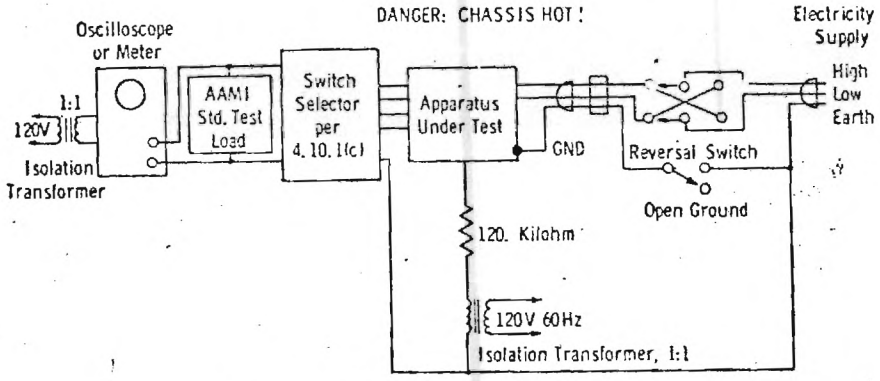

FIG. 8. Test circuit 3 (paragraph 4.10.1 (c)).

4.10.2 *Standard Test Loads*

All tests of sections 4.11 shall be performed using the following AAMI Standard test loads (Figs. 3 and 4), or equivalent test loads constructed with R_1 in the range 500 to 1500 ohms.

$$500 \text{ ohms} \leq R_1 \leq 1500 \text{ ohms}$$

When R_1 has a value other than 1000 ohms, C_1, R_2, and R_3 must be scaled as follows:

$$C_1 = (0.15\ \mu\text{f})\ (100 \text{ ohms}/R1)$$
$$R_2 = (5.11 \text{ ohms})\ (R1/1000 \text{ ohms})$$
$$R_3 = (52.3 \text{ ohms})\ (R1/1000 \text{ ohms})$$

These test loads shall be constructed using 1% tolerance or better metal film type resistors and a 5% tolerance or better mica or plastic dielectric (extended foil) capacitor.

The standard test loads have an impedance-frequency characteristic, shown in Figure 5, that is the approximate inverse of the allowed risk current versus frequency curves (Figs. 1 and 2).

4.10.3 *Standard Test Circuits and Procedure*

The tests described in 4.10.1 (a), (b), and (c) shall be performed using the type A load for type A apparatus and using the type B load for type B apparatus.

The individual apparatus under test shall be connected as in test circuits 1, 2, and 3 and subjected to the corresponding tests of 4.10.1 (a), (b), and (c). The test shall be first made with an oscilloscope to test for the presence of d-c, transient, or a-c risk currents. The individual apparatus risk current is given in total frequency-weighted microamperes by:

$$I\ (\mu a) = E\ (\text{mv, RMS})/R_1\ (\text{kilohms})$$

The values of I so determined shall be equal to or less than:

Type A: 10 μa, RMS
Type B: 500 μa, RMS

Except that, the stated limit for risk current from the type A apparatus chassis (4.10.1 (a)) may be exceeded when the electricity supply chassis grounding contact is open, provided that such risk current does not exceed 50 μa. Apparatus using this exclusion shall be marked to indicate the necessity for proper grounding, and shall meet all requirements of this standard when properly grounded. This exception shall apply to any product of a single manufacturer capable of operation from a single connection to the electricity supply of the premises, or to products that are in such close physical proximity to constitute a single instrument effectively.

4.11 *Decontamination and Sterilization*

It is recommended that equipment not exceed the above risk current limits due to repeated exposures to the method of sterilization or disinfection described by the manufacturer.

NFPA No. 76B-T Tests

304. Grounding Circuit Continuity.

3041. Measurement of Resistance. The resistance of the grounding circuit in the cord and the plug, measured from the grounding pin of the plug to the exposed metal surfaces of the appliance or to its chassis, shall not exceed 0.15 ohms at the time of manufacture, and during the life of the appliance.

305. Leakage Current.

3051. Definition of Leakage Current. The term leakage current shall refer to the currents as measured in the tests of 3054. These currents usually derive from the line power by resistive paths, or capacitive or inductive coupling. However, they also include currents from other sources generated within the appliance that are measured by these tests. The numerical values set forth in 3052 shall apply for the life of the appliance.

3052. Leakage Current Limits. Leakage current limits in 3052 are based on acute events as described in Chapter 1, i.e., sensation, duration tetany, or ventricular fibrillation. Appliance design should aim to reduce such current as much as possible. In properly grounded appliances maximum chassis leakage current is in the grounding conductor and not through the patient. Where currents are deliberately introduced into the patient for long periods, low level effects must be considered (*see 306*), and the limits appropriately reduced.

30521. Appliances Not in Contact with Patient. Appliances which are not intended to contact a patient (e.g., housekeeping or maintenance appliances, such as vacuum cleaners or hand tools), shall not exceed 500 microamperes of chassis leakage current as measured in 30542. The governing body of the hospital shall establish precautionary procedures when such appliances are to be used in a patient vicinity. (*See A–30521.*)

30522. Appliances Likely to Contact the Patient. Cord connected appliances which are likely to contact the patient shall not exceed 100 microamperes of chassis leakage current as measured in 30542. Appliances with leads that are applied to the patient shall not have leakage in patient leads in excess of 50 microamperes. These leakages are measured in accordance with 30543 and 30544. (*Exception: See 30523.*)

30523. Appliances with Isolated Patient Leads. An isolated patient lead is a patient lead which has high impedance between itself, ground, and each power line. Only isolated patient leads shall be connected to intracardiac catheters or electrodes. The leakage current from isolated patient leads of appliances or fixed equipment as measured in accordance with 30543, 30544 and 30545, shall not exceed 10 microamperes. Only appliances meeting this requirement shall be identified as having isolated patient leads.

30524. Permanently Wired Equipment. Permanently wired equipment installed in the patient vicinity shall not have leakage current from the frame to ground in excess of 0.5 milliamperes. The leakage current shall be measured prior to installation while the equipment is temporarily insulated from ground. After installation the appropriate voltage limits of Chapter 2 shall be met.

30525. Frequency of Leakage Current. The leakage current limits stated in 3052 shall be RMS values for essentially D.C. and sinusoidal waveforms to 1 KHz. (*See Figure A–30525.*) For fre-

quencies above 1 KHz the leakage current limit shall be the value given in 3052 multiplied by the frequency, in KHz, up to a maximum multiplier of 100. The limits for non-sinusoidal periodic, modulated, and transient waveforms remain to be determined.

30526. Leakage Current in Relation to Polarity. Leakage current limits shall not be exceeded when the polarity of the power line is correct or reversed, with power to the appliance "on" and "off", and with all operating controls in the most disadvantageous position.

30527. Leakage Current During Fault. The Leakage current limits shall not be exceeded by more than a factor of 2 for any probable and nonobvious fault. (*See 30547.*) A nonobvious fault occurs with failure of any single component, or cascaded failure of any other components resulting from the failure of that single component, in which the fault would not cause an obvious malfunction during the normal operation of the appliance. An obvious malfunction is one which would be indicated by an audible or visible signal, abnormal meter reading, or some malfunctioning of the equipment necessitating correction before proceeding with further operation of the appliance. A probable fault is a fault caused by the failure of a component having a mean time between failure (see Mil Handbook 217A) that is substantially less than the specified useful working life of the appliance. Leakage current limits under probable and nonobvious fault conditions are generally predetermined by design and type testing, and are not usually determined in the field.

3053. Tests Prior to Leakage Tests. Preliminary safety tests shall be made before undertaking the leakage current test procedures of 3054. Care shall be exercised in performing these tests since the operator may be exposed to the full line voltage if the appliance is faulty.

30531. Measurement of Integrity of Grounding Circuit. Resistance measured between the grounding pin of the plug and exposed metal parts of an appliance shall meet the requirements of 3041.

30532. Measurement of Resistance to Ground. Resistance measured between each current-carrying blade of the plug and the grounding pin of the plug with the power switch of the appliance in the "on" and "off" position shall be greater than 1 megohm.

3054. Leakage Current Tests.

30541. Techniques of Measurement. Each test shall be per-

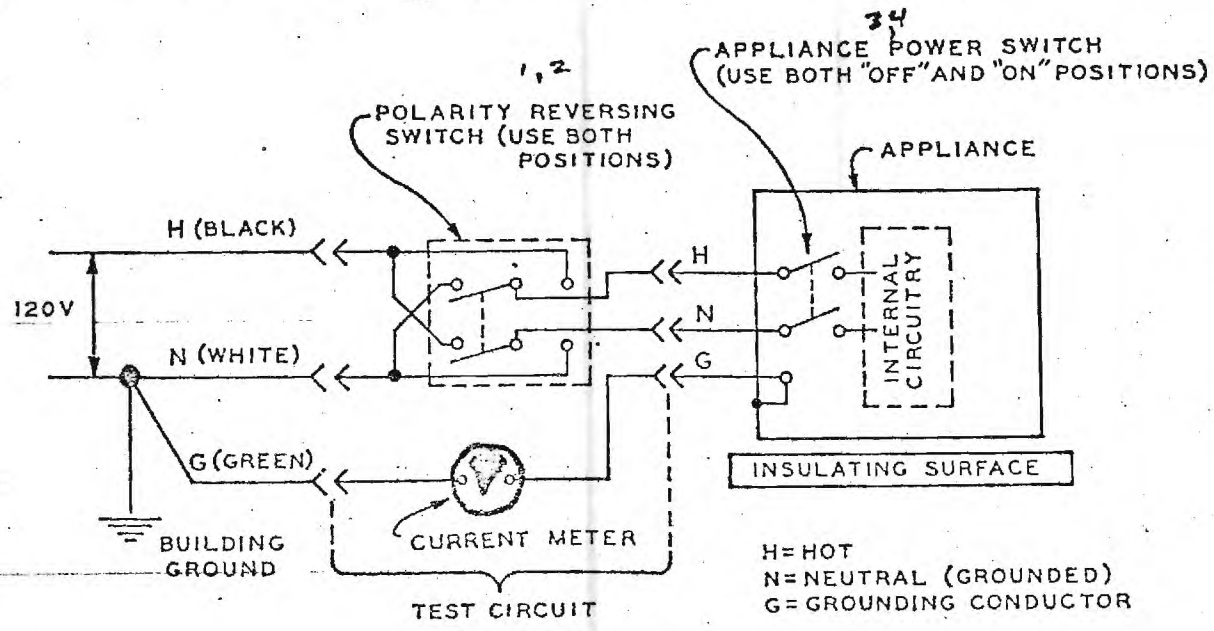

Figure 30542. Test 1

formed with the appropriate connection to a properly grounded AC power system. The measuring instrument shall be a current measuring device of 1000 ohms impedance or less that shall measure the leakage current as described in 30525. (*See A-30541.*)

30542. Leakage Current Between Exposed Metal and Ground. The first test measures the current from the exposed metal surfaces of an appliance to ground. The source of this current is usually the AC power line. The current is measured from exposed metal to ground with the grounding prong of the 3-wire power cord disconnected from the grounding pole of the outlet receptacle. The current meter is inserted between the exposed metal surfaces and ground. The tests shall consist of four measurements: the appliance power switch "on" and "off" and the polarity reversing switch in alternative positions. (*See Figure 30542.*)

305421. Appliances with Nonconductive Cases. When the appliance has no exposed conductive surface, one shall be simulated by placing a 10 x 20 cm., bare metal foil in intimate contact with the exposed surface. This shall be considered the "exposed metal surface" of the appliance and all appropriate tests shall be performed to the foil. This test is intended to apply to appliances with approved nonconductive surfaces. When the insulation is not an approved material, the underlying surface shall be tested as in 30542.

30543. Leakage Current Between Patient Leads and Ground. The second test measures the current to ground from individual and interconnected patient leads. The test shall be made with the patient leads active (e.g., in the case of a cardiograph, the lead selector switch shall be advanced to an operating position and not left in the standardizing position). This test shall consist of four measurements: the appliance power switch "on" and "off" and the polarity reversing switch in alternative positions. (*See Figure 30543.*)

30544. Leakage Between Leads. The third test measures the current between any pair of patient leads or any single lead and all the others. (*See Figure 30544.*)

30545. Leakage Between Isolated Patient Leads and Ground. The fourth test measures the effective impedance between each patient lead and ground for an appliance with isolated patient circuitry. The current in an isolated lead is measured by applying an external source of power line frequency and voltage between the lead and ground. Suitable safety precautions (such as including a resistance in series to limit the current, and insulation of the meter) must be taken to protect the operator. (*See Figure 30545.*) In appliances without a power cord or with ungrounded exposed conductive surfaces, measurements shall be made with the exposed conductive surfaces temporarily grounded. If there is no exposed conductive surface, measurement shall be made with a simulated surface as described in 305421 which is also temporarily grounded.

30546. Applicability of Measurements. The limits in Sections 30521 through 30525 for nonfault conditions shall apply for the manufacturers' final test, and during the life of the appliance.

30547. Leakage Current Under Fault. The current limits given under fault conditions shall be calculated by the manufacturer from design data or shall be determined from manufacturers' type tests with deliberate faults introduced in the apparatus.

30548. Appliances or Appliance Appendage Likely to be Wet During Use in Bed by Risk II or Risk III Patients. Any electric appliance or appendage that may be taken into the patient's bed by design or accident is to be capable of meeting the leakage current limits in 3052 while immersed in a 3 percent (by weight) sodium chloride solution with power "on" for at least one hour. A metal plate of 25 sq. cm., immersed in the salt solution with the appliance or appendage, is considered the equivalent of a patient lead.

CHAPTER 3. ELECTRICAL APPLIANCES

301. General.

This chapter provides standards for the design and construction of electric appliances intended for use in patient care areas. These standards apply to all electric appliances including medical appliances as well as household type appliances, such as lamps, radios, television receivers, hair driers, vacuum cleaners, floor polishers, hand tools, etc. These standards describe features of design and construction related to safety and do not cover performance, operational protocol, or efficacy of the appliance except as these may affect safety.

Hospital service presents unusual mechanical and environmental problems. Appliances are frequently moved on carts, lifted on or off shelves, and hand carried. Hospital service is equivalent to hard industrial use under wet conditions, additional requirements for flammable anesthetizing locations are published in NFPA No. 56A.

This chapter describes protection of the patient and operator against electric shock resulting from direct or indirect contact with power line or other hazardous voltages, and discusses protection against the more subtle shock hazards that may result from resistive, inductive or capacitive leakage current.

This chapter provides for the inspection of appliances used in hospitals and is a guide for designers and testing organizations in the establishment of specific requirements and testing procedures for safety.

302. Governing Body Responsibility

It shall be the responsibility of the governing body of the hospital to establish policies and procedures related to the safe use of electric appliances in that institution. This shall include types of power distribution and grounding systems, specifications of appliances and supervision of patient treatment procedures, as well as procedures for procurement, and maintenance of the appliances.

The requirements of this chapter assume that the appliance will be used in the environments described in Chapter 2 and under the administrative and maintenance requirements of Chapter 4.

303. Requirements for All Electric Appliances

3031. Mechanical Construction.

30311. Electric appliances shall be designed to withstand the handling and abuse likely to be encountered in hospitals or clinics without introducing thermal, electric or mechanical hazards due to collapse of the enclosure or displacement of parts.

30312. The enclosure shall be designed to prevent the dispersion outside its confines of molten metal, burning insulation, or flaming particles, etc., generated under fault conditions.

30313. The enclosure shall be designed to restrict the entrance of insects and vermin.

30314. The enclosure shall be designed to restrict the insertion of pens, pencils, paper clips, knives, and similar objects into those portions of the equipment where a hazard could result.

30315. The appliance shall be designed to exclude spilled or splashed liquids from internal electric parts while in a normal operating, transport or storage position.

30316. Any electric appliance or appendage of an appliance that is likely to be taken into the patient's bed shall be designed to meet the test requirements in 30548 while immersed in a 3 percent (by weight) sodium chloride solution with power "on" for at least one hour.

30317. The appliance shall be mechanically stable in the position of normal use. If the appliance is intended for use in an anesthetizing location, 4516 (c) of NFPA No. 56A–1973, Inhalation Anesthetics, applies.

3032. Electrical Requirements.

303201. Attachment Plugs. Attachment plugs of an approved type shall be used on all cord connected appliances (*See ANSI C73.13 and C73.17, and 410–5 of NFPA No. 70–1971.*) Except as provided for special locations, this plug shall be a 2-pole, 3-wire grounding type. (*See 2038 and 303205.*) The grounding prong shall be constructed so that it cannot be easily broken. The grounding prong of the plug shall be the first to be connected and the last to be disconnected. If screw terminals are used, the stranded conductor shall be twisted and tinned or shall be attached by an approved terminal lug. The power cord conductors shall be arranged so that the conductors are not under tension in the plug. The grounding conductor shall be the last one to disconnect when a failure of the plug's strain relief allows the energized conductors to be disrupted. (*See A303201.*)

Strain relief shall be provided. The strain relief shall not cause thinning of the insulation on any conductor. The strain relief of replaceable plugs shall be capable of being disassembled. Plugs may be bonded to the cord jacket if the design is listed for any application.

The wiring of each cord assembly shall be tested for continuity and polarity at the time of manufacture, when assembled into an appliance, when repaired, and periodically as designated by the hospital administration. (*See 3041.*)

Adapters may be used to permit appliances fitted with distinctive plugs to be used with conventional power receptacles. The wiring of the adapter shall be tested for polarity and continuity of grounding at the time of manufacture, when repaired, and periodically as designated by the hospital administration. (*See 3041.*)

303202. Power Cords. "Hard Service" (SO or STO) or "Junior Hard Service" (SJO or SJTO) or equivalent listed flexible cord shall be used (*See Table 400–11 of NFPA No. 70–1971*). "Hard Service" cord is preferable when it may be subject to mechanical abuse. The jacket of a cord shall be appropriate for exposure to oil, oxygen, ozone, etc., and filler strands shall be nonwicking. A cord length of 10 feet is recommended for general locations, and 18 feet for operating rooms, but may be shorter if designed for a specific location.

The flexible cord, including the grounding conductor, shall be of a type suitable for the particular application, listed for use at a voltage equal to or greater than the rated power line voltage of the appliance, and have an ampacity, as given in Table 400–9 (b), NFPA No. 70–1971, equal to or greater than the current rating of the device.

The grounding conductor shall be no smaller than No. 18 AWG. The conductors of cords longer than 10 feet shall be no smaller than No. 16 AWG.

An in-line switch shall not be used in a power cord unless it is listed for the purpose and where applicable meets the requirements of 30316.

303203. Appliance Strain Relief. Appliance strain relief shall be provided at the attachment of the power cord to the appliance so that mechanical stress, either pull, twist, or flexion, is not transmitted to internal connections. If the strain relief is molded on the cord, it shall be bonded to the jacket, and shall be of comparible material.

303204. Separable Cord Sets. A separable power cord set with an approved means of connection to the appliance may be used if it can be shown that an accidental disconnection is unlikely or not dangerous. Separable power cord sets shall be designed so that the

grounding conductor is the first to be connected and the last to be disconnected. Cord set plugs and receptacles are to be polarized in accordance with ANSI C73.13 and C73.17.

303205. Wiring of Power Cords. Power cords, regardless of whether intended for use on grounded or isolated power systems, shall be connected in accordance with the conventions of a grounded system. *(See 200-2 to 200-10 of NFPA No. 70-1971.)*

The circuit conductors in the cord shall be connected to the plug and the wiring in the appliance so that any of the following devices used in the primary circuit is connected to the unidentified conductor; the center contact of an Edison base lampholder; the center contact of a fuseholder; any other single pole, overcurrent protective device; and any other single pole, current interrupting device. The identified (white) conductor shall be used only as the neutral conductor and the green (or green with yellow stripes) conductor shall be used only as the grounding conductor. No other conductor shall be white or green. *(See Note to 210-5(b) of NFPA No. 70-1971.)* The grounding conductor shall be connected to the exposed metal or frame of the appliance by a separate terminal or bolt so that a reliable electric connection is made. The connection shall permit ready replacement of the cord and be arranged so that it will not be broken during electric or mechanical repair of the appliance. *(See A-303205.)* The power cord conductors shall be arranged so that the grounding conductor is the last to disconnect when a failure of the strain relief at the appliance allows the cord to be pulled free. When a grounding conductor is not required, the appliance shall be visibly labeled to indicate that fact. If the power cord of an appliance does not contain a grounding conductor it shall not be fitted with a grounding type plug.

303206. Protection of Wiring in Appliances. Within the appliance, the power conductors of the cord and the associated primary wiring (other than the grounding conductor) shall be mounted and dressed to minimize the likelihood of accidental contact with the frame or exposed conductive parts of the appliance.

303207. Grounding of Exposed Metal. All exposed conductive surfaces of an electric appliance likely to become energized from internal sources, shall be bonded together to provide electric continuity with the connection to the grounding conductor. If the exposed conductive surfaces are likely to become energized from external sources, they shall be connected to a grounding conductor regardless of the isolation of those surfaces from internal electric components.

303208. Power Control Switch. The power control switch of an appliance shall interrupt simultaneously all power conductors, including the neutral (identified) conductor. The grounding conductor shall not be interrupted.

303209. Overcurrent Protection. A listed overcurrent protective device shall be used in the power input circuit of all appliances. The overcurrent device may be placed in the attachment plug, the power cord, or in the main body of the appliance, and shall precede any other components including the primary control switch. No other component except listed insulated terminal blocks or connecting devices shall be used ahead of this overcurrent device. This shall not preclude the use of subsidiary overcurrent protective devices within the appliance. The power control switch and overcurrent device may be combined into one component provided it is identified to indicate the combined function to the operator.

303210. Insulation of Patient Circuits. Patient-connected circuits within an appliance shall be sufficiently separated or insulated from all other circuits within the appliance to prevent accidental contact with hazardous voltages or currents.

303211. Avoidance of Connections with Grounding Conductor. Any component such as a filter or test circuit, within an appliance, that intentionally reduces the impedance between the energized conductors and the grounding conductor, shall be approved for the purpose, and shall be in operation when the leakage current tests specified in 305 are performed. (*Also see 20383*)

3033. Line Voltage Variations and Transients.

30331. The expected performance of an appliance designed to provide life support functions shall not be disturbed by transients, line voltage variations, or other electric interference to a hazardous degree.

Line voltage variations shall not exceed the limits of *ANSI C84.1, Voltage Ratings for Electric Power Systems and Equipment.* (*Also see 209*)

3034. Thermal Standards.

30341. Electric appliances not designed to supply heat to the patient, and operated within reach of a nonambulatory patient, shall not have exposed surface temperatures in excess of 50°C. Surfaces maintained in contact with the skin of patients and not intended to supply heat shall not be hotter than 41°C, or 2°C higher than ambient air temperature, whichever is higher.

3035. Toxic Materials.

30351. Surfaces that contact patients shall be free of materials which commonly cause toxic reactions. Coatings used on these surfaces shall conform to *ANSI Z66.1, Paints and Coatings Accessible to Children to Minimize Dry Film Toxicity.*

3036. Chemical Agents.

30361. Devices containing hazardous chemicals shall be designed to facilitate the replenishment of these chemicals without spillage, and shall protect the patient, the operating personnel, and the safety features of the appliance from such chemicals.

NOTE: Preference should be given to the use of replaceable sealed canisters of chemicals over loose chemicals.

3037. Fire and Explosion Hazards.

30371. Materials used in the construction and supplies for appliances shall be nonflammable or flame retardant, and impermeable to liquids and gases to the extent practicable. Materials used in the operation of appliances may be combustible when essential to their intended function.

30372. Oxygen-Enriched Atmospheres. Apparatus employing oxygen, or which is intended to be used in oxygen-enriched atmospheres, shall comply with *NFPA No. 56B, Respiratory Therapy; NFPA No. 53M, Oxygen-Enriched Atmospheres; NFPA No. 56D, Hyperbaric Facilities;* and *NFPA No. 56E, Hypobaric Facilities.*

30373. Anesthetizing Location. Electric appliances used in anesthetizing locations shall comply with the provisions of *NFPA No. 56A, Inhalation Anesthetics.*

309. Low Voltage Appliances.

3091. Appliances and instruments operating from batteries or their equivalent, or an external source of low voltage, shall conform to all applicable conditions of this chapter. This shall include communications, telephone, signaling, entertainment, remote control, and low energy power systems.

3092. Rechargeable Appliances. Battery-operated appliances that are rechargeable while in use shall meet all the requirements of 305 for line-operated appliances.

3093. **Low Voltage Connectors.** Attachment plugs used on low voltage circuits shall have distinctive configurations which do not permit interchangeable connection with circuits of other voltages.

3094. **Isolation of Low Voltage Circuits.** Low voltage circuits shall be electrically isolated from the power distribution system by an approved means.

310. Instruction Manuals and Labels.

3101. Operator's or user's manuals shall be supplied with all units. These manuals shall include operating instructions, maintenance details, and testing procedures.

The manuals shall include the following:

(1) Illustrations which show location of controls,

(2) Explanation of the function of each control,

(3) Illustrations of proper connection to the patient and other equipment,

(4) Step-by-step procedures for proper use of the appliance,

(5) Safety considerations in application and in servicing,

(6) Effects of probable malfunction on safety,

(7) Difficulties that might be encountered, and care to be taken if the appliance is used on a patient simultaneously with other electric appliances,

(8) Schematics, wiring diagrams, mechanical layouts and parts list for the specific appliance as shipped,

(9) Functional description of the circuit, and

(10) Power requirements, heat dissipation, weight, dimensions, output current, output voltage, and other pertinent data.

A-303201 — Connection of Grounding Conductor to the Attachment Plug. Should the strain relief of an attachment plug fail in such a manner that tension on the power cord is transmitted to the connections between the cord conductors and the plug terminals and one or more connections fail it is essential that the last connection to fail is the one to the appliance grounding wire. This may be accomplished by making the grounding wire longer than the other conductors (such that it is the last wire to receive the strain) or by clamping or otherwise arranging the ungrounded wires in such a manner that they are the first to break.

A-303205 — Connection of Grounding Conductor to Exposed Metal or Frame of the Appliance. The appliance end of a power cord must have a strain relief to prevent tension on cord from being transmitted to the power cord connections inside the appliance. Should this strain relief fail it is essential that the last connection to fail is the one to the appliance grounding wire. This may be accomplished by making the grounding wire longer than the other conductors (such that it is the last wire to receive the strain) or by clamping or otherwise arranging the ungrounded wires in such a manner that they are the first to break.

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To facilitate the ready replacement of a damaged line cord it is essential that the connection between the power cord grounding wire and the appliance's exposed metal or frame be easy to make without the use of special tools.

At the same time it is important that this grounding wire be attached in such a manner that it is unlikely to be disturbed while making other repairs. Accordingly the grounding conductor should be attached to the exposed metal or frame of the appliance, with a machine screw, locking washer, nut and grounding terminal or lug (other equivalent removable fasteners may be used). A green hexagonal head screw is preferred as a means of identification. If used, the screw should be of size No. 6 for AWG 16 or 18 conductors, No. 8 for AWG 14 wire and No. 10 for AWG 12 to 8 wire. The attachment area should be free of paint, rust, etc. The screw should not be used for any structural or assembly purposes. Where feasible, the screw should be located interior to the device in such a manner that it cannot be removed without first removing access covers or hardware. Any internal circuit grounding wires that are to be connected to the exposed metal or frame should be connected to a screw adjacent to the power cord grounding wire screw. An additional bonding wire may be connected between the internal circuit grounding wires and the power cord grounding wire so as to insure grounding under conditions where vibration may loosen the attachment screws.

3.3.3 Grounding.

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3.3.3.1 Attachment Cord Plugs. All line operated instruments shall be supplied with replaceable plugs providing separate power and chassis ground connections. For instruments operated on 120 volt power, the plug shall be a three terminal plug (hot line, power ground and chassis ground). Hubbell plug #23034 or equal to mate with Hubbell wall recipitical #23030 unless otherwise specified.

Chapter 4. Equipment for General Use

ARTICLE 400 — FLEXIBLE CORDS AND CABLES

A. General and Types

400-1. General. Flexible cords and cables and their associated fitting shall be suitable for the conditions of use and location.

400-2. Types. Cords of the several types shall conform to the descriptions of Table 400-11. Types of flexible cords other than those listed in Table 400-11 and other uses for types listed in the Table, shall be the subject of special investigations and shall not be used before being approved.

400-7. Minimum Size. The individual conductors of a flexible cord or cable shall be not smaller than the sizes shown in Table 400-11.

Table 400-9(b). Ampacity of Flexible Cord

Table 400-9(b) gives the allowable ampacity for not more than 3 current-carrying conductors in a cord. If the number of current-carrying conductors in a cord is from 4 to 6, the allowable ampacity of each conductor shall be reduced to 80 percent of the values for not more than 3 current-carrying conductors in the Table. A conductor used for equipment grounding and a neutral conductor which carries only the unbalanced current from other conductors, as in the case of normally balanced circuits of 3 or more conductors, are not considered to be current-carrying conductors. Where a single conductor is used for both equipment grounding and to carry unbalanced current from other conductors, it shall not be considered to be a current-carrying conductor. (See Section 250-60.)

(Based on Ambient Temperature of 30°C (86°F). See Section 400-9 and Table 400-11)

Size AWG	Rubber Types TP, TS	Rubber Types PO, C, PD, E, EO, EN, S, SO, SRD, SJ, SJO, SV, SVO, SP		Types AFS, AFSJ, HC, HPD, HSJ, HSJO, HS, HSO, HPN SVHT	Types AVPO AVPD	Cotton Types CFPD*
	Thermoplastic Types TPT, TST	Thermoplastic Types ET, ETT, ETLB, ETP, ST, STO, SRDT, SJT, SJTO, SVT SVTO, SPT				Asbestos Types AFC* AFPD*
		At†	Bt†			
27**	0.5	..	..	..	..	..
18	..	7	10	10	17	6
17	..	..	..	12	..	..
16	..	10	13	15	22	8
15	..	..	..	17	..	..
14	..	15	18	20	28	17
12	..	20	25	30	36	23
10	..	25	30	35	47	28
8	..	35	40	..	..	..
6	..	45	55	..	..	..
4	..	60	70	..	..	..
2	..	80	95	..	..	..

* These types are used almost exclusively in fixtures where they are exposed to high temperatures and ampere ratings are assigned accordingly.

** Tinsel Cord.

† The ampacities under sub-heading A are applicable to 3-conductor cords and other multi-conductor cords connected to utilization equipment so that only 3 conductors are current carrying. The ampacities under sub-heading B are applicable to 2-conductor cords and other multi-conductor cords connected to utilization equipment so that only 2 conductors are current carrying.

NOTE 1. Ultimate Insulation Temperature. In no case shall conductors be associated together in such way with respect to the kind of circuit, the wiring method employed, or the number of conductors, that the limiting temperature of the conductors will be exceeded.

NOTE 2. SVHT made only in No. 18 and 17 AWG sizes.

(Continued from page 184)

individual conductors at least 45 mils in thickness, unless Type S, SO, ST or STO cord is used.

400-9. Overcurrent Protection and Ampacities of Flexible Cords.

Flexible cords not smaller than No. 18, and tinsel cords, or cords having equivalent characteristics, of smaller size approved for use with specific appliances, shall be considered as protected against overcurrent by the overcurrent devices described in Section 240-5. Cords shall be not smaller than required in Table 400-9(b) for rated current of the connected equipment.

400-10. Pull at Joints and Terminals. Flexible cords shall be so connected to devices and to fittings that tension will not be transmitted to joints or terminal screws. This shall be accomplished by a knot in the cord, winding with tape, by a special fitting designed for that purpose, or by other approved means which will prevent a pull on the cord from being directly transmitted to joints or terminal screws.

Notes to Table 400-11

1. Except for Types PO-1, PO-2, PO, SP-1, SP-2, SPT-1, SPT-2, TP, TPT, and AVPO, individual conductors are twisted together.

2. Type PO-1 is for use only with portable lamps, portable radio receiving appliances, portable clocks and similar appliances which are not liable to be moved frequently and where appearance is a consideration.

3. Types TP, TPT, TS, and TST are suitable for use in lengths not exceeding 8 feet when attached directly, or by means of a special type of plug, to a portable appliance rated at 50 watts or less and of such nature that extreme flexibility of the cord is essential.

4. Rubber-filled or varnished cambric tapes may be substituted for the inner braids.

5. Types S, SO, ST, and STO are suitable for use on theater stages, in garages and elsewhere, where flexible cords are permitted by this Code.

6. Traveling cables for operating, control and signal circuits may have one or more nonmetallic fillers or may have a supporting filler of stranded steel wires having its own protective braid or cover. Cables exceeding 100 feet between supports shall have steel supporting fillers, except in locations subject to excessive moisture or corrosive vapors or gases. Where steel supporting fillers are used, they shall run straight through the center of the cable assembly and shall not be cabled with the copper strands of any conductor.

Types E, EO, EN, ET, ETP, ETLB, and ETT cables may incorporate in the construction No. 20 gauge conductors formed as a pair, and covered with suitable shielding for telephone and other audio or higher frequency communication circuits. The insulation of the conductors may be rubber or thermoplastic of thickness specified for the other conductors of the particular type of cable. The shield shall have its own protective covering. This component may be incorporated in any layer of the cable assembly, and shall not run straight through the center.

7. A third conductor in these cables is for grounding purposes only.

8. The individual conductors of all cords except those of heat-resistant cords (Types AFC, AFPD, AFS, AFSJ, AVPO, AVPD and CFPD) shall have a rubber or thermoplastic insulation, except that the grounding conductor where used, shall be in accordance with Section 400-14(b). A rubber compound shall be vulcanized except for heater cords (Types HC, HPD and HSJ).

Table 400-11. Flexible Cord
(See Section 400-2)

Trade Name	Type Letter	Size AWG	No. of Conductors	Insulation	Braid on Each Conductor	Outer Covering	Use		
Parallel Tinsel Cord	TP See Note 3	27	2	Rubber	None	Rubber	Attached to an Appliance	Damp Places	Not Hard Usage
	TPT See Note 3	27	2	Thermo-plastic	None	Thermo-plastic	Attached to an Appliance	Damp Places	Not Hard Usage
Jacketed Tinsel Cord	TS See Note 3	27	2 or 3	Rubber	None	Rubber	Attached to an Appliance	Damp Places	Not Hard Usage
	TST See Note 3	27	2 or 3	Thermo-plastic	None	Thermo-plastic	Attached to an Appliance	Damp Places	Not Hard Usage
Asbestos-Covered Heat-Resistant Cord	AFC	18–10	2 or 3	Impreg-nated Asbestos	Cotton or Rayon	None	Pendant	Dry Places	Not Hard Usage
			2		None	Cotton, Rayon or Saturated Asbestos			
	AFPD		2 or 3						
Cotton-Covered Heat-Resistant Cord		18–10	2 or 3	Impreg-nated Cotton	Cotton or Rayon	None	Pendant	Dry Places	Not Hard Usage
			2		None	Cotton or Rayon			
	CFPD		2 or 3						

See Notes 1 through 8 preceding table.

Table 400-11 continued

Trade Name	Type Letter	Size AWG	No. of Conductors	Insulation	Braid on Each Conductor	Outer Covering	Use		
Parallel Cord	PO–1	18	2	Rubber	Cotton	Cotton or Rayon	See Note 2	Dry Places	Not Hard Usage
	PO–2	18–16					Pendant or Portable		
	PO	18–10							
All Rubber Parallel Cord	SP–1	18	2	Rubber	None	Rubber	Pendant or Portable	Damp Places	Not Hard Usage
	SP–2 See Note 7	18–16	2 or 3						
	SP–3 See Note 7	18–12		Rubber	None	Rubber	Refriger-tors or Room Air Condi-tioners	Damp Places	Not Hard Usage
All Plastic Parallel Cord	SPT–1	18	2	Thermo-plastic	None	Thermoplastic	Pendant or Portable	Damp Places	Not Hard Usage
	SPT–2 See Note 7	18–16	2 or 3						
All Plastic Parallel Cord	SPT–3 See Note 7	18–10		Thermo-plastic	None	Thermoplastic	Refriger-ators or Room Air Condi-tioners	Damp Places	Not Hard Usage

See Notes 1 through 8 preceding table.

Table 400-11 continued

Lamp Cord	C	18–10	2 or more	Rubber	Cotton	None	Pendant or Port.	Dry Places	Not Hard Usage
Twisted Portable Cord	PD	18–10	2 or more	Rubber	Cotton	Cotton or Rayon	Pendant or Port.	Dry Places	Not Hard Usage
Vacuum Cleaner Cord	SV, SVO	18	2	Rubber	None	Rubber	Pendant or Portable	Damp Places	Not Hard Usage
	SVT,	18–17		Thermopl		Thermoplastic			
	SVTO See Note 7	18	2 or 3						
Heat Resistant V.C. Cord	SVHT	18–17	2	Thermopl	None	Thermoplastic	Pendant or Portable	Damp Places	Not Hard Usage
Junior Hard Service Cord	SJ	18–16	2, 3, or 4	Rubber	None	Rubber	Pendant or Portable	Damp Places	Hard Usage
	SJO					Oil Resistant Compound			
	SJT SJTO			Thermopl or Rubber		Thermoplastic			
Hard Service Cord	S See Note 5	18–2	2 or more	Rubber	None	Rubber	Pendant or Portable	Damp Places	Extra Hard Usage
	SO					Oil Resist. Compound			
	ST			Thermopl or Rubber		Thermoplastic			
	STO					Oil Resistant Thermoplastic			

See Notes 1 through 8 preceding table.

410-55. Grounding-Type Receptacles, Adapters, Cord Connectors and Attachment Plugs.

(a) Receptacles, cord connectors and attachment plugs of the grounding type shall be provided with one fixed grounding member in addition to the circuit members.

Exception: The grounding contacting member of grounding-type attachment plugs on the power supply cords of portable hand-held, hand-guided or hand-supported tools or appliances may be of the movable self-restoring type on circuits operating at not to exceed 150 volts between any two conductors nor 150 volts between any conductor and ground.

(b) Grounding-type receptacles, adapters, cord connectors and attachment plugs shall have a means for connection of a grounding conductor to the grounding member. A terminal for connection to the grounding member shall be designated by:

(1) A hexagonal headed or shaped terminal screw or nut, not readily removable, and green colored; or

(2) A pressure wire connector which has a green-colored body (a wire barrel); or

(3) A similar green-colored connection device in the case of adapters. The grounding terminal of a grounding adapter shall be a green-colored rigid ear, lug, or similar device. The grounding connection shall be so designed that it cannot make contact with current-carrying parts of the receptacle, adapter, or attachment plug. The adapter shall be polarized.

(4) If the terminal for the equipment grounding conductor is not visible, the conductor entrance hole shall be marked with the word "Green" or otherwise identified a distinctive green color.

(c) In no case shall a grounding terminal or grounding-type device be used for purposes other than grounding.

(d) Grounding-type attachment plugs and mating cord connectors and receptacles shall be so designed that the grounding connection is made before the current-carrying connections. Grounding-type devices shall be designed so grounding members of attachment plugs cannot be brought into contact with current-carrying parts of receptacles or cord connectors.

D. Electrically Susceptible Patient Areas

517-50. General. It is the purpose of Part D to specify the performance criteria and/or wiring methods which will minimize the hazard by the maintenance of adequately low-potential differences between conductors which could be contacted by a patient even when pertinent inherent equipment leakage currents exceed 10 microamperes.

In a health care facility, it is not feasible to prevent the occurrence of a conductive or capacitive path from the patient's body to some grounded object, because that path may be established accidentally or through instrumentation directly connected to the patient. All other electrically conductive surfaces which may make an additional contact with the patient, or other instruments which may be connected to the patient, then become possible sources of electrical currents which can traverse the patient's body. When the current path includes a small area of direct contact with the heart, a current in excess of 10 microamperes could be hazardous. Unless special precautions are taken, the power-line-frequency impedance of the patient circuit, which includes the internal conduction path through a small contact area, could be as low as 500 ohms when measured at low-current magnitudes. Under these conditions a voltage difference between the points of patient contact in excess of 5 millivolts also is considered hazardous.

517-51. Performance.

(a) In electrically susceptible patient areas the maximum 60-hertz alternating-current potential difference between any two conducting surfaces within the reach of a patient, or those persons touching the patient, shall not exceed 5 millivolts measured across 500 ohms under normal operating conditions or in case of any probable failure.

E. Inhalation Anesthetizing Locations

For further information regarding safeguards for anesthetizing locations, see Inhalation Anesthetics Standard, NFPA No. 56A-1971.

517-60. Hazardous Areas.

(a) Any room or space in which flammable anesthetics or volatile flammable disinfecting agents are stored shall be considered to be a Class I, Division 1 location throughout.

(b) In a flammable anesthetizing location the entire area shall be considered to be a Class I, Division 1 location, which shall extend upward to a level 5 feet above the floor.

517-61. Wiring and Equipment Within Hazardous Areas.

(a) In hazardous areas as defined in Section 517-60, all fixed wiring and equipment, and all portable equipment, including lamps and other utilization equipment, operating at more than 8 volts between conductors, shall conform to the requirements of Sections 501-1 through 501-15 and Sections 501-16(a) and (b) for Class I, Division 1 locations. All such equipment shall be specifically approved for the hazardous atmospheres involved.

(b) Where a box, fitting or enclosure is partially, but not entirely, within a hazardous area, the hazardous area shall be considered to be extended to include the entire box, fitting or enclosure.

(c) Flexible cords, which are or may be used in hazardous areas for connection to portable utilization equipment, including lamps operating at more than 8 volts between conductors, shall be of a type approved for extra-hard usage, shall be of ample length, and shall include an addi-

References

1. Tentative Standard for the Safe Use of Electricity in Patient Care Facilities, NFPA-NO. 76B-T, National Fire Protection Association, Boston, 1973, 96 pp.

2. "Recommended AAMI Safety Standard for Electromedical Apparatus," Association for the Advancement of Medical Instrumentation Subcommittee on Electrical Safety, Arlington, Va., 1971, 8 pp.

3. USA Standard C1-1971: National Electrical Code (NFPA No. 70), National Fire Protection Association, Boston, 1971, 536 pp.